



Whitepaper

Change Management in Biopharma Manufacturing.

Managing the People Side of
Transformation.

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1. Exploiting Potential.

With the evolution of biopharmaceutical manufacturing in combination with new technologies of digital and data, pharmaceutical manufacturers often find themselves in large transformations to prepare for the future.

As these programs heavily impact the way of working, from the SOPs followed by employees on the shop floor to the decision-making of top management, managing the people side of change is a key success factor.

A structured approach integrated in project management processes and well established experienced Organizational Change Managers are the key for successful transformations to avoid running out of budget or time.



2. Transformations and Projects in Manufacturing.

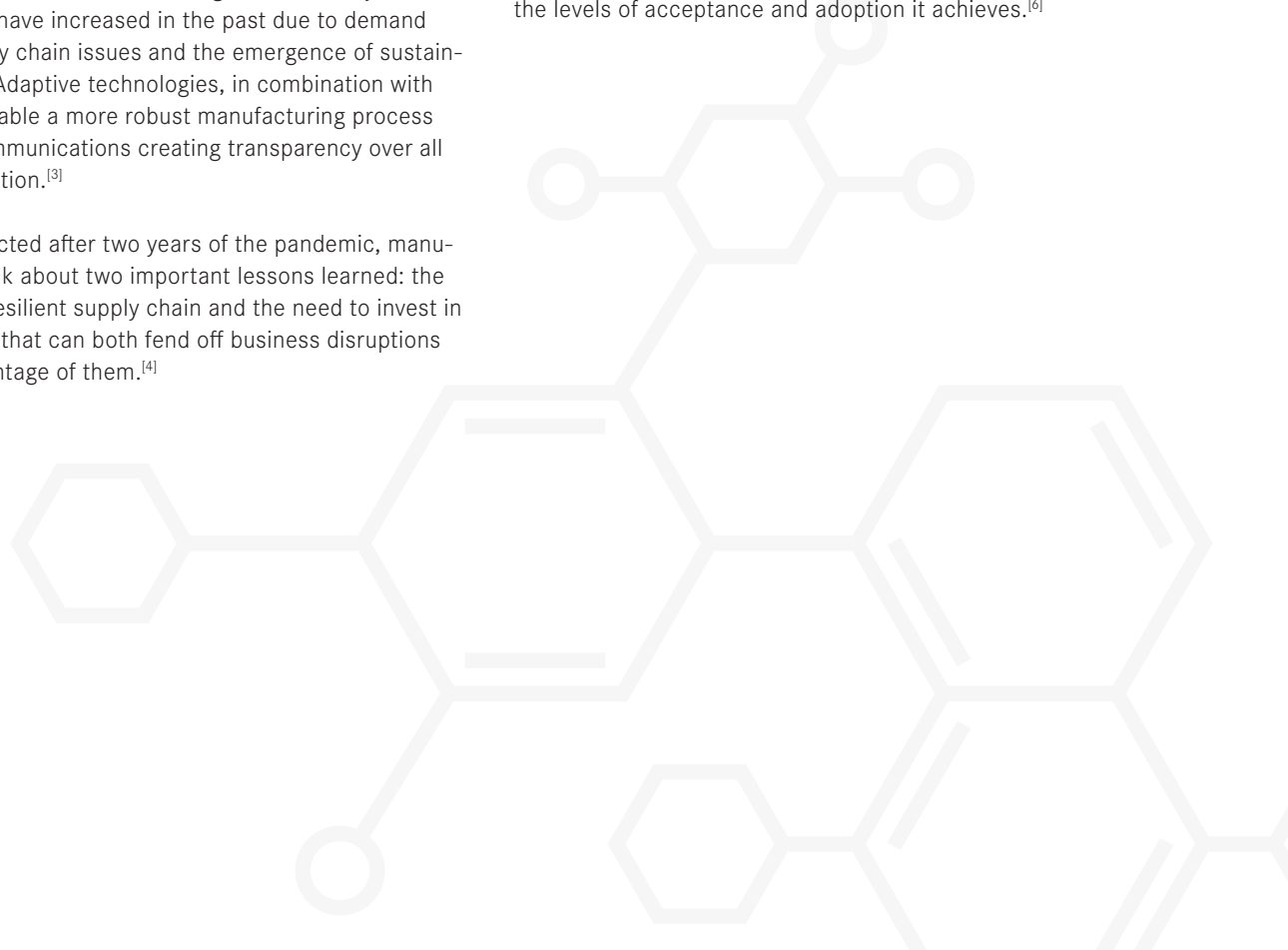
Over the past decades, complex manufacturing of sophisticated drug products and dosage forms has evolved in parallel to the development of new types of medicines. In addition, the possibilities of Industry 4.0 have a major impact on the design of factories and production processes. Automation, robotics, artificial intelligence, machine learning and advanced connectivity challenge previous approaches and business models.^[1]

The ability that companies have to make their production more flexible, agile, efficient and of higher quality can help them to respond faster to market changes and thereby reduce their risks, which have increased in the past due to demand disruptions, supply chain issues and the emergence of sustainability matters.^[2] Adaptive technologies, in combination with data analytics, enable a more robust manufacturing process and seamless communications creating transparency over all aspects of production.^[3]

In a survey conducted after two years of the pandemic, manufacturing CEOs talk about two important lessons learned: the importance of a resilient supply chain and the need to invest in new technologies that can both fend off business disruptions while taking advantage of them.^[4]

However, the introduction of these new technologies requires great efforts from manufacturers and the implementation of complex transformation projects lead to noticeable changes for employees across all levels.^[5] And whenever we see programs having a greater impact on people, we hear about budget overruns, extended durations, and results that don't meet expectations in terms of realized potential and adoption.

Fortunately, a change in the way of thinking is now taking place. We perceive a shift from solely focusing on hardware to a more comprehensive approach that takes into account the people side of change, so that successful implementation is judged by the levels of acceptance and adoption it achieves.^[6]





3. Challenges Managing the People Side of Transformation.

As in other industries or organizations, transformation programs in biopharma manufacturing face similar challenges. Changes are causing resistance, management politics and a different stakeholder perspective, resulting in a loss of project efficiency, or making communication difficult to conduct in a way that everyone understands and internalizes the key messages.

In addition, organizations implementing innovations in a highly regulated environment need to cope with some additional challenges such as limited time for changes during regular

shutdowns, GMP requirements, work regulations and limited access to shop floor workers in terms of communications technology.

And finally, challenges emerge from the transformation itself (Figure 1). Ever shorter turnaround cycles and real-time decision-making lead to less room for human error, automation demands workers to shift their focus from conducting predefined tasks to a more strategic, supervising role, and robots may even replace jobs.

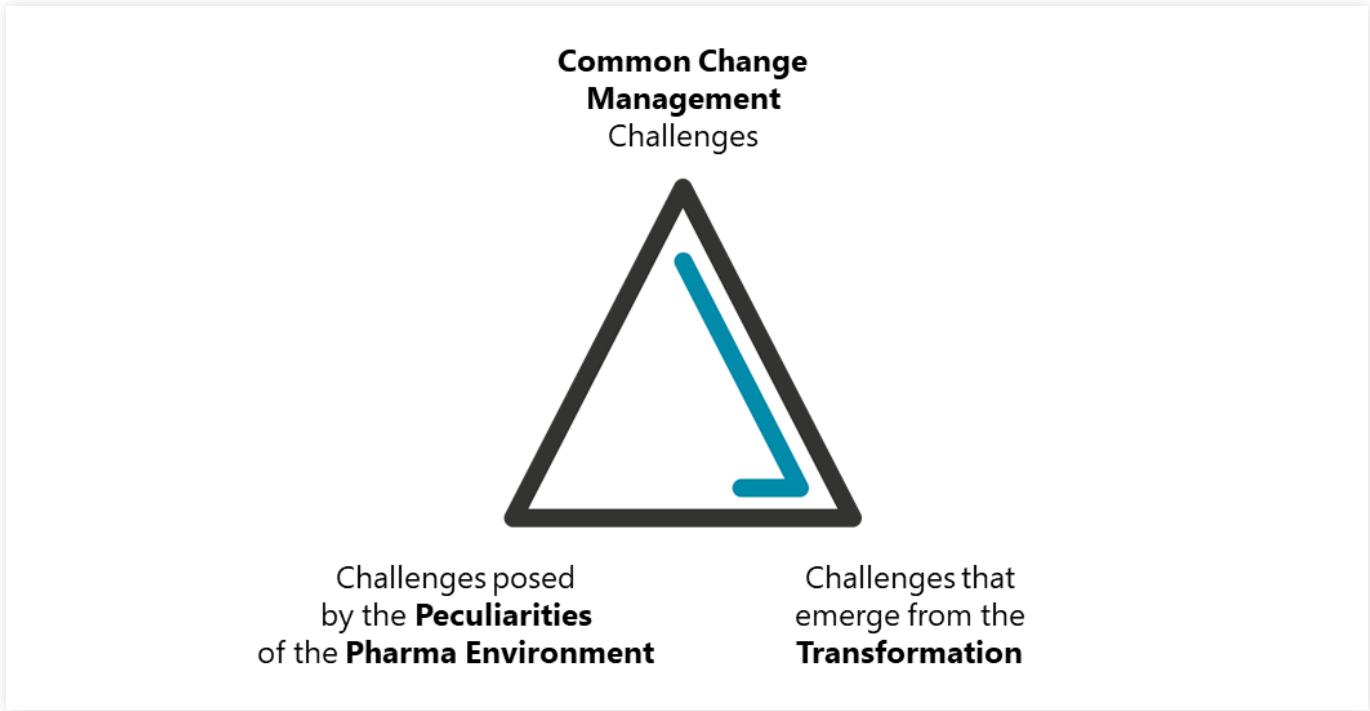


Figure 1: Challenges Managing the People Side of Transformation - three perspectives

4. Successfully Implement Change Management in a Project.

To cover every perspective of the people side of transformation, we're following a well-established framework composed of seven dimensions. This known framework, which has proven its applicability and effectiveness in numerous client projects, has an important characteristic: it's not just a theoretical concept. Our approach is not just focusing on the framework but also seeing how it is implemented and used.



Case for Change

Bring all decision makers together to explain them the reasons for the change and verbalize an explicit purpose. An early alignment on target picture, needed capabilities, change story and key messages allows a convincing communication to all impacted units such as engineering, production, packaging, and quality during the change.



Leadership Alliance

Create a common understanding for the change and its reasons – from top management (e.g., site and unit leadership) to middle management (supervisors, etc.) to win their commitment for the change. Empower management to drive the change and motivate their employees to engage in the change through targeted Change Management measures.



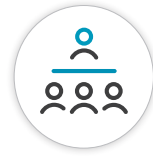
Stakeholder Involvement

Identify project individual key stakeholders among top leaders, middle management and shop floor, and analyze the change impact on them. Set up measures to involve stakeholders in the change journey to ensure quality, acceptance, and adoption.



Communication

Set up a communication plan and effective communication tools that meet the individual needs and conditions of the target groups (like shop floor workers) regarding channel and cadence. Find suitable solutions to engage with employees in production areas where they have limited access to the organization's interaction channels.



Training

Design training concepts that ensure a sustainable learning curve for employees. Effective formats reaching beyond SOP trainings and enable employees, characterized by different learning types, in the long run.



Business Readiness Management

Define KPIs to measure and monitor project success along the way and consequently ensure the detection of gaps quickly, and promptly define counteracting measures. KPIs can demonstrate outcomes both objectively with production figures or subjectively via structured employee feedback, for example. In both cases, it's crucial to provide insights in time proximity to the change. Summary metrics at the end of a process such as ROI, capacity increase, or cost reduction are rather inappropriate as they do not depend on the change alone and take too long to measure the impact.



Sustainability

Create the framework conditions to establish the new behaviors in day-to-day business over the long term. Build up change management expertise within the organization to achieve long-term success.

Following these dimensions not only gives us the certainty of having all aspects of the people side of change covered but it provides us with guidance on where to start and where to end. However, it's not a step-by-step guide and we perceive it more as a cyclic linkage where we need to have iterations of planning, implementations, checks and corrective measures within every dimension (Figure 2).

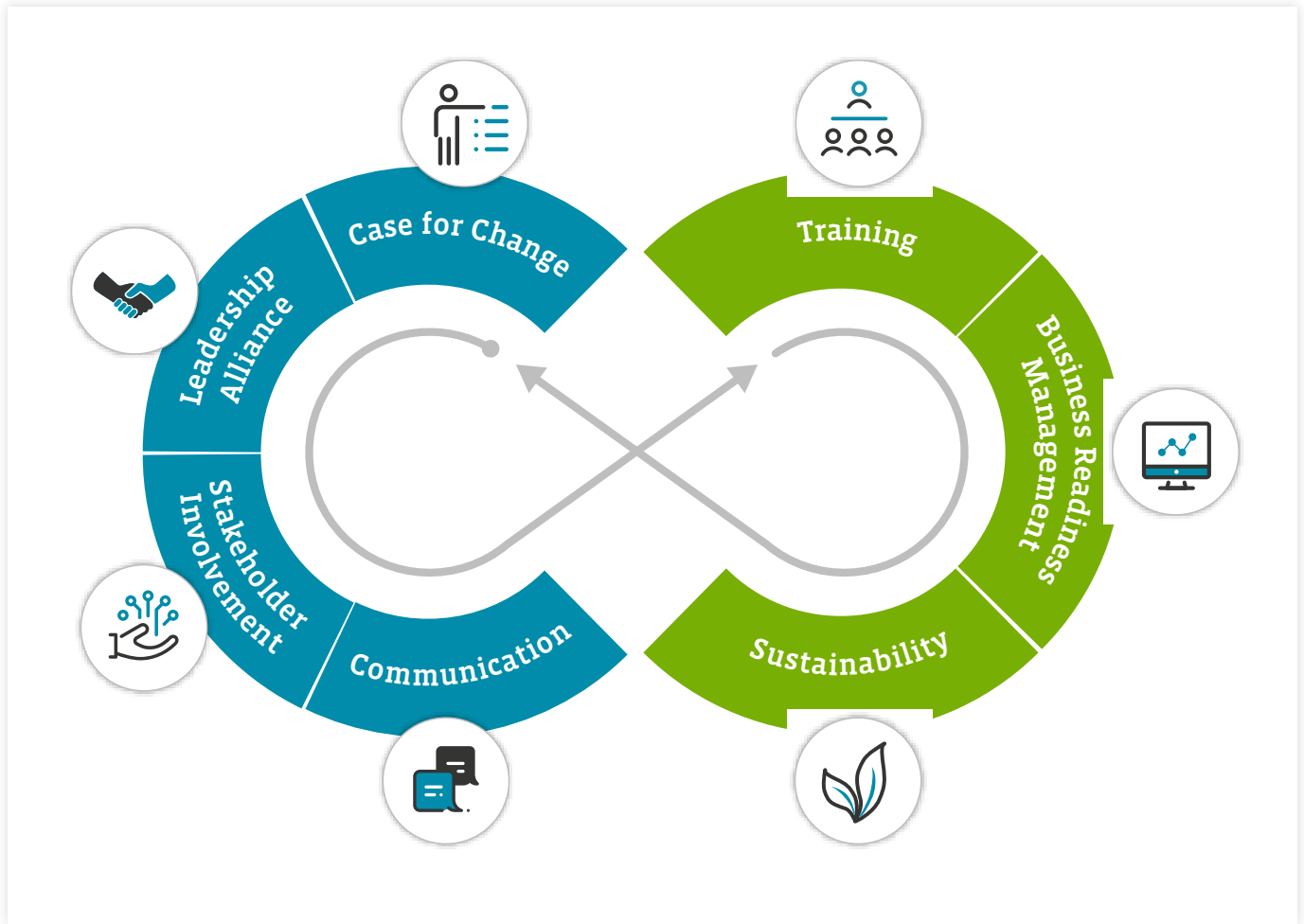


Figure 2: Campana & Schott Change Management Framework

However, understanding the framework is just the starting point on the pathway to a successful implementation.

Applying this framework to a project requires:

- A comprehensive toolbox of methods, measures, and templates for every dimension,
- An experienced change manager able to select and implement the tools in the sense of best practices, and
- The fundamental willingness of at least one sponsor and project manager to integrate Change Management into the project.



5. Change Management in Large Multi-site Transformation Programs.

It gets even more complex, the more projects, teams and factories are involved in the transformation. Thus, Change Management is not a question of implementing a framework

in specific projects, but of building a culture of change within the organization. We tackle this challenge with a multi-stage approach:



Create awareness among the site leadership in all sites. The more they understand the extent of Change Management's influence on the success of a transformation at their site, the easier it will be to include middle management into Change Management and get the resources for local implementation.



Establish Change Management experts who are available at every site and support project teams to set up and support the Change Management approach for specific projects. In larger organizations, we recommend a center of excellence.



Build Change Management capabilities across the organization. Starting with, but not limiting it to PMOs and the transformation program team, and including middle management, HR or Communications.



Enable project teams to analyze Change Management needs on their own and consider basic aspects in their project. A playbook or integrated operating model can be provided to project managers as a guidance.



Monitor the adoption of the Change Management framework.





6. Conclusion.

Change Management is a key success factor for large transformations in pharma manufacturing. With a dedicated framework in place, companies can address the specific challenges of biopharma manufacturing and the pace of change in this area much more efficiently and with a higher level of realized potential.

However, successful Change Management depends on the ability to implement the framework into projects and establish

a progressive culture of change. Experienced Change Managers need to drive the comprehensive and targeted application of the framework and bring sponsors, project teams and the entire organization along on the journey towards the transformation.

Whether you are trying to manage the people side of change in a major transformation project or in multi-project situations, Campana & Schott supports you with expertise and well-proven best practices.





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