Operational Excellence in the Pharma Industry

Professionalizing - Embedding - Sharpening

Focus - The role and perception of operational excellence (OPEX) within the pharmaceutical industry has changed significantly over the last decade. Concepts that are applied in numerous companies have evolved from single, standalone approaches with a rather limited scope towards sophisticated programs aiming to deliver an organization's competitive edge.

Since 2003, the University of St. Gallen has accompanied the industry's development with its ongoing benchmarking study supporting decision-making in pharmaceutical companies.

The History and Definition of Pharmaceutical OPEX

The philosophy of operational excellence looks back on a long history. The underlying concepts that evolved over time have their origins predominantly in the Japanese automotive industry and disseminated thence into most other industries. However, with regard to the pharmaceutical industry, the history of OPEX is still short. The first serious initiatives were only launched at the beginning of this century. Since then, OPEX gained momentum and became a priority for top management and workforce alike at pharmaceutical manufacturers in every part of the world.

Around the same time, science of pharmaceutical manufacturing appeared on the U.S. Food and Drug Administration's (FDA) agenda. As a reaction to a continuously rising number of post-approval changes that hampered the agency's inspection obligations, the FDA started to push the industry towards developing a scientific understanding of pharmaceutical manufacturing processes and encouraged manufacturers to use innovative technologies like process analytical technology (PAT) for better process control leading to a new paradigm: Quality and productivity came on the agency's agenda, providing the industry with new opportunities and paving the way for OPEX. The incremental introduction of OPEX in the pharmaceutical industry up until now has happened in three major stages (fig. 1).
Looking back at the historical development of OPEX in the pharmaceutical industry and the numerous influences over time, it is no wonder that there is no clear-cut definition of the term "operational excellence" to date.

In the past, the term OPEX was often used for newly launched improvement activities or as a proxy for cost-cutting programs, Six Sigma and lean initiatives.

With regard to the innumerable publications that contributed to the understanding of OPEX and from our experience, OPEX should be understood as the balanced management of cost, quality and time while at the same time focusing on the customer needs. To achieve this end, OPEX comprises structural and behavioral changes thought to optimally support necessary activities. In order to maintain sustainability also in changing or volatile environments, OPEX has to be pushed by top management and has to be designed to engage every single employee.

Obviously, OPEX is not only about performance. It also encompasses the way leading to that superior performance, and practices that allow an organization to continuously improve itself.

**Launching And Maintaining OPEX**

The focus of managing an OPEX initiative has to change over time. Awareness of critical success factors and barriers in managing OPEX can provide guidelines as to how to design, review and adapt an excellence program. Obviously, launching an initiative and introducing a company to continuous improvement for the first time addresses another set of managerial capabilities than maintaining a system in a steady state. The comparison of successful practices with less favorable ones results in a summary of barriers and success factors that managers should have on their agenda when launching an OPEX initiative.

After the effective launch of an OPEX initiative, its management will need to change. However, this does not imply to disregard the factors that were once relevant for the initiative's successful take-off. They should be further stressed, but complemented by paying attention to new challenges and utilizing upcoming opportunities (fig. 2).

An OPEX initiative has to be aligned with a company's overall manufacturing and supply strategy. Consequently, in accordance with a constantly changing environment that an organization is exposed to as well as with changing maturity levels of manufacturing sites and the initiative itself, a time-based adaption of OPEX programs along with their focused priorities is required. Figure 2 summarizes
essential focal areas OPEX managers should be aware of in order to lead an initiative successfully in the long run. Over time, new areas to focus on will arise, at the same time existing focal areas might require an adaption.

The necessity of an occasional adaption of an OPEX program or rather its time-based alignment and review of conformity with an organization's overall targets becomes obvious while reviewing the decade-long evolution of successful industry practices. Such programs usually have their origin in focused and single-point process improvements and later include the entire organization in the transformation process towards a full system approach.

**Professionalizing And Embedding OPEX**

The same way an organization changes over time, the embedded OPEX organizational structure will need to be developed. Since it is the organizational structure that provides the framework for the social-operational-control system and beyond influences behavior of individuals and groups, organizational sub-dimensions will require an adjustment at the right time in order to accelerate the sustainable implementation of OPEX (fig. 3).

Although Werani (2013) argues that there are several options to design a manufacturing organization, especially in a globally operating company, Friedli and Lembke (2013) conclude that literature lacks evidence of the right structure and the guideline for practitioners as to how to optimally staff an OPEX initiative neither on its launch nor in its maintaining phase. Every company, however, needs to develop its own and specific organizational model including the right structures in order to ensure a reasonable division of labor and to facilitate productivity and efficiency gains.

Despite the pharmaceutical industry is discussing product and process optimization for more than a decade, predominately these discussions are still following a single plant perspective.

The coordination of pharmaceutical manufacturing sites on a network level holds enormous potential. Therefore, the industry will have to follow the example of other more advanced manufacturing industries and systematically address production optimization from a true network perspective in the near future.

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