

Innovations in the Pharmaceutical Industry

Guest Editorial

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The pharmaceutical industry is one of the world's most important production sectors. However, over the last decades, pharmaceutical companies have been facing the urgent need to improve and keep their performances under tight control, an activity they are historically behindhand with, compared to other sectors, such as food or electro-mechanical industries. The increasing speed of new product development, the intensity of early generic competition, the exposure to loss of revenue following patent expiration, the higher regulatory hurdles on top of a declining R&D productivity – especially when compared to the biotech industry – presented a future with lower growth prospects than in the past for the pharmaceutical industry. Those players who tried to react to this negative contingency through merger and acquisition operations, had later found themselves in critical conditions in terms of coordination difficulties and excess of capacity in several production plants scattered all over the world. Now, this industry has to demonstrate that it can deliver better returns on investment than in the past by changing many aspects of how it has operated up until now. Indeed, this means aligning to a process which started years ago in several other industries: pharmaceutical companies must concentrate on all those factors that can allow them to operate cost reduction without decreasing quality and service level, while simultaneously pushing for the introduction of new products, which is one of the most

relevant competition drivers for the pharma industry. Other industries have proved that it is possible to leverage process efficiency to spur innovation, help open new market opportunities, and shift cost and risk paradigms. Pharmaceutical companies that are at the leading edge of process excellence are likely to emerge as the true winners.

In the call for papers, we asked for submissions on the latest significant innovative results in the pharmaceutical industry, encouraging research that uses empirical and case study approaches to present theories, techniques, applications and practical experiences in increasing the efficiency or effectiveness of pharmaceutical processes. We requested contributions covering all topics in the area of management, including the full range of production, distribution, logistics, operations and innovation management. All contributions were double-blind peer reviewed according to the usual, high standard of the journal. 14 papers were selected and included in the Special Issue and most of them show interesting applications to real companies as case studies.

Several different topics have been addressed with regards to the operations research stream. Silvestri et al. approached a problem of packaging line optimization by checking for missing components and minimizing false rejects of packages, and proposing two weighing

algorithms for verifying the content of pharmaceutical packages of different components. Benedetti et al. approached the problem of buffer design trying to conciliate performance improvement and cost reduction. The application of their proposal to a pharmaceutical packaging line has led to a buffer size reduction of about 50% in an extremely simple, fast and effective way, allowing decreasing costs and space utilization while maintaining all buffer-related benefits. De Carlo et al. also concentrated on the analysis of the production line, evaluating whether throughput and work in process diagrams can be useful for controlling its behaviour. Through the application to an industrial case, they managed to show the effectiveness of their proposal, which led to the identification of improvement actions that were estimated to raise the value of OEE by three percentage points. In a second paper, the same authors presented another contribution including a critical view of the traditional OEE calculation claiming that, while this well-known indicator is suitable to measure the performance of a single machine, in complex systems a simulation should be used rather than an analytical approach. On the same stream, Nenni et al. presented a detailed description of a successful case of Lean Management implementation with a hybrid Kanban-Conwip system, obtaining a reduction of 37% in the work-in-progress level and of 5 days in the total pipeline lead time, over 90 days.

Debora Sarno et al. submitted a contribution in the logistic theme, showing the economic convenience of centralizing the hospitals' inventory decisions based on the sharing of medical prescriptions of patients along the supply chain. Results are impressive, showing that there may always be cost savings in data sharing and centralized decisions, even without the exploitation of price-quantity discounts, or varying the period of central pharmacy orders aggregation or completely avoiding the physical centralization of stocks.

On the maintenance side, two contributions were accepted: one by De Felice et al., who focused on maintenance strategies using a multi object approach and offers significant insights useful for the analysts to improve maintenance management and maintenance software requirements' definition. The other by Duraccio et al., who assessed the impact of maintenance-oriented design for a production line which included operations in a clean room. Their study showed significant benefits in terms of performance and system availability and the payback of the investment they proposed as a redesign of a bottling machine resulted to be less than 6 years.

Then, two other papers addressed specific topics that have become of primary importance for pharmaceutical

companies over the last few years, which are traceability and compliance to international standards: Benedetti et al. focused on the impact of traceability regulations on production processes and logistics, presenting both criticalities and benefits of the technological implementation of these requirements and drawing a path to the efficient application of Track and Trace and serialization techniques. They managed to show how serialization can not only improve private companies' competitive advantage, but also contribute to security and people's quality of life. Differently, De Minicis et al. presented a step-by-step approach to assess the compliance to the ANSI/ISA-88 batch production standard along with a BPM-oriented methodology applicable to the redesign of any generic recipe development process. This contribution can be of extreme importance for pharmaceutical companies aiming to speed up the new product's introduction process or easing technology transfers between different plants.

Innovation management was instead the focus of Peruffo et al., who performed an explorative case study to show how spin offs can help firms explore new opportunities for innovation and showed evidence for both a potential success case and an unhappy strategic choice. Then several papers are dedicated to the influence of network effect on innovation and performance: D'Alise et al. concentrated on the impact of clusters and networks involving industrial, academic and institutional players in the pharmaceutical setting, applying a social network analysis (SNA) approach. Their conclusions provide useful insights to increase the managerial capabilities with reference to clusters' formation. Capo et al. dealt with new business models through the observation of a network of firms operating at different stages of the pharmaceutical supply chain, and stressed the need for pharmaceutical companies to effectively interact with the government and university laboratories and research centres. Battistoni et al. proposed a network model to identify the main drivers of consumer-based brand equity and applied it to OTC drugs in the Italian self-medication market. Their model can help pharmaceutical companies address the most effective drivers in order to improve their presence in the market and to exploit the potential value of their advertising.

I am grateful to all the authors who submitted their contributions for publication in this Special Issue. I would also like to acknowledge the tremendous efforts of the reviewers: they greatly contributed to the quality of the final manuscripts and they managed to complete their review on time despite a tight publication schedule. Finally, I would like to thank the Managing Editor Ms. Dragana Manestar for her precious support for this Special Issue.