Pharmaceutical Manufacturing and Health Information Technology:
A Reflection About Lean Six Sigma and Industry 4.0

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Beatriz Maria Simões Ramos da Silva
https://orcid.org/0000-0001-7121-0871
Institute of Drugs Technology, Oswaldo Cruz Foundation, Brazil

Vicente Aguilar Nepomuceno de Oliveira
Federal University of the State of Rio de Janeiro, Brazil

Jorge Magalhães
https://orcid.org/0000-0003-2219-5446
Global Health and Tropical Medicine (GHMT), IHMT, NOVA University of Lisbon, Portugal

INTRODUCTION

Health is considered a global public good. It is not exclusive, that is, that no one or any collectivity is excluded from its possession or consumption. Also, its benefits may be available to all people. There is also an apparent consensus that health is not competitive, and that there is no rivalry, that is, one person's health cannot be at the expense of excluding other people (Hartz, 2012).

Medicines are highly complex products, in a sector of intense technology and innovation. In the Brazilian health system, there is private and public production of medicines. They do not compete with each other, but are complementary, given that the public production of medicines, by Public Pharmaceutical Laboratories (LFO – Brazilian term), is mainly dedicated to diseases of no interest to private pharmaceutical laboratories (Magalhães et al., 2008b). The LFOs make up a national public heritage to produce medicines. They contribute to the supply of medicines to the public sector, especially those intended for endemic diseases that afflict the most vulnerable population, without great commercial interest for the private sector (Figueiredo et al., 2020).

The pharmaceutical sector is one of the most capital-intensive areas of the economy. In its activities, it presents relevant investments in Research, Development & Innovation (R, D & I). In this aspect, this sector is only surpassed by the arms industry (Magalhães et al., 2008a; Gadelha, 2003). The pharmaceutical industry's contribution to global health is extraordinary. By the year 2022, spending on medicines by the world population is expected to reach US$ 1.5 trillion and the sector's revenue will be about US$ 370 billion higher than in 2016. According to IQVIA Institute for Human Data Science (2022), there is a prospect for drug spending growth of around 6% by 2023, most of which will occur in developed markets driven by the areas of oncology, autoimmune diseases and diabetes. However, this industrial segment faces adversities, which drive the adoption of business strategies, such as Lean Six Sigma, widely used in almost all types of industries. The motivations for its implementation are: reducing costs, increasing profits, improving operational performance, optimizing quality, achieving competitive advantage, among others (Siregar et al., 2019).

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Integrating Industry 4.0 with Lean Six Sigma can maximize the results that are achieved by each separate approach, providing significant gains (Filho et al., 2020). According to Arden et al. (2021), pharmaceutical companies are transitioning from industry 2.0 to 3.0, with the exception of some companies that have already adopted the latter. Destro & Barolo (2022) reports that implementation of Industry 4.0 by pharmaceutical organizations has been slow. However, regulatory agencies have been driving the use of data science, as well as the adoption of other technological innovations (Food and Drug Administration [FDA], 2019; Arden et al., 2021).

In this chapter, the fundamentals of Lean Six Sigma and Industry 4.0 are presented and the combined use of these methodologies is investigated due to their complementary relationship. Additionally, the benefits and limitations of these approaches in the pharmaceutical industry are explored, as well as the difficulties to implement them in the context of this industrial segment.

BACKGROUND

Almost two decades ago, the pharmaceutical industry began to face a series of adversities: declining productivity in Research & Development; increasing regulatory requirements; novel and more complex therapies, such as personalized medicine; increasing competition and complexity; pressure to reduce drug prices and more recently, a high number of recalls and shortages due to quality problems (Yu & Kopcha, 2017). Additionally, it was found that the performance of production processes was inferior to that of other types of industry, presenting high variability and consequently large fluctuations in cycle times; high scrap and rework rates and elevated quality costs. These challenges imposed the need to make manufacturing more agile, flexible and efficient, without increasing costs. It was necessary for the pharmaceutical industries to adopt operational excellence and continuous improvement programs, implemented long before in other industrial segments (Basu, 2010).

In 2002, the Food and Drug Administration (FDA) launched the "Pharmaceutical Current Good Manufacturing Practices for the 21st Century: a Risk-Based Approach". This initiative aims improving and modernizing manufacturing and product quality regulations. With input from academia and industry, the FDA has built a vision for pharmaceutical manufacturing and quality for the 21st century: a maximum-efficiency, agile, and flexible pharmaceutical manufacturing sector that reliably manufactures high-quality medicines, without the need for extensive regulatory oversight (Yu et al., 2016). In subsequent years, the FDA and other regulatory agencies have been participating in "International Conferences on Harmonization of Technical Requirements for Registration of Pharmaceuticals of Human Use" (ICHs) with the aim of developing guidelines to make drug regulatory processes more efficient, such as example:

a) ICH Q10: provides a harmonized model for a pharmaceutical quality system, which promotes continuous improvement throughout the life cycle of the product (Basu, 2010).
b) ICH Q12: provides a framework to facilitate the management of post-approval chemistry, manufacturing and controls changes in a more predictable and efficient manner across the product lifecycle (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use [ICH], 2021).

Adherence to the initiative and the guidelines cited is advantageous for industries as it reduces production costs and the number of defective products and guarantees greater flexibility with regulatory authorities to implement changes and improvements (FDA, 2007; FDA 2018).