Leading Pharmaceutical Operational Excellence
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Outstanding Practices and Cases

Springer
Almost 25 years have gone since we established the expression “lean production” for a set of Japanese techniques which changed the whole competitive landscape of the automotive industry in the 1990s. This in turn led to fundamental changes in how production is managed in industry after industry.

Back in 2006, I wrote the foreword to the book *Operational Excellence in the Pharmaceutical Industry* just as the pharmaceutical industry began its own lean journey, which showed that “lean thinking” knows no industry barriers. I’m glad that the story continued, and if I look at some of the approaches described in the current book, I see an Industry that puts a lot of sophistication and resources in its journey towards Operational Excellence. It has also finally realized that sustainability comes with people and not with tools.

This reminds me of our own lean journey from *The Machine That Changed the World* to *Lean Thinking* and *Lean Solutions* and to establishing the Lean Global Network (www.leanglobal.org). If pharmaceutical companies want to stay ahead of competition, they should have a look at the new evidence presented in this book and draw their conclusions!

Lean Enterprise Academy, UK

Prof. Dr. Daniel T. Jones
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Part I
Introduction
Chapter 1
Introduction to Leading Operational Excellence: Making OPEX a Competitive Weapon

Thomas Friedli and Prabir Basu

Do not follow where the path may lead. Go instead where there is no path and leave a trail.
Harold R. McAlindon

Not the cry, but the flight of a wild duck, leads the flock to fly and follow.
Chinese Proverb

Go to the people. Learn from them. Live with them. Start with what they know. Build with what they have. The best of leaders when the job is done, when the task is accomplished, the people will say we have done it ourselves.
Lao Tzu

If your actions inspire others to dream more, learn more, do more and become more, you are a leader.
John Quincy Adams

In our second book on Operational Excellence in the Pharmaceutical Industry titled The Pathway to Operational Excellence, published in 2010, we had undertaken an imaginary journey to develop the framework and structure of the book.\(^1\) It gave us the opportunity to describe our experiences from working with dozens of different pharmaceutical manufacturers in the US and Europe. We suggested a sequence starting with preparing for the journey and finishing with the re-definition of the destination leading to the selection of the next destination so that the journey will be an on-going one. Two years later, we have decided to write another book. The main

\(^1\) For inspiration we investigated the similarities between our Journey and one of the Journeys of Captain James Cook undertaken in the eighteenth century. (cf. Friedli et al. (2010), p. 1ff.)

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reason for doing this is the positive feedback we have received on the first two books. The other reason is our conviction that despite the renewed enthusiasm for outsourcing in the industry, manufacturing will remain a critical activity for every major pharmaceutical company, and the continuous improvement of manufacturing will not just be an option, but a necessity.

The concept for this book is somewhat similar to the last book but in some respects, is very different. The similarity is that we again present academic perspectives on OPEX along with industrial perspectives so that the book can facilitate direct insights into practical applications. However, we have structured the book differently this time in order to describe how some of the most advanced travelers in the world overcame the distances and mastered the challenges along their way. This book illustrates some of the best approaches we have seen while researching OPEX and provides a guideline as to how to really improve and close some of the existing gaps in one’s own OPEX approaches. Thus, the book is a collection of successful practices in Pharmaceutical OPEX.

The title “Leading Operational Excellence” was chosen deliberately. On the one hand, it gives us the opportunity to look for and to find “leading practice examples”. On the other hand, we could dig deeper into the true leadership requirements for a successful and sustainable implementation of Operational Excellence, being fully aware that this is often the most critical part of the whole implementation process.

To set the stage, our book begins with an introductory part where we provide an overview of where the pharmaceutical industry started with OPEX, its current level of operational performance, the biggest gaps in OPEX implementation and the challenges ahead. We also describe the importance of OPEX in today’s pharmaceutical environment and how OPEX has become a topic in every major pharmaceutical company in this world. To make it clear early on what we understand by conducting research or talking about Operational Excellence, we provide our definition of Operational Excellence. The main reason for doing this is that in some companies Operational Excellence has unfortunately become synonymous with “cost cutting”. But true Operational Excellence is something totally different. Friedli and Bellm start by defining OPEX and describing the importance of it for the Pharmaceutical Industry. Friedli and Werani highlight the major milestones in the short history of Operational Excellence in the pharmaceutical industry. Werani is one of the first pharmaceutical manufacturing plant leaders who introduced “lean”, and then became one of the formative designers of the Right First Time Excellence Program at Pfizer. Friedli is one of the first academics conducting research on the various aspects of OPEX in the pharmaceutical industry. They bring together their perspectives to explain the rise of OPEX in the pharmaceutical industry. Friedli, Lembke, Güttner and Schneider (University of St.Gallen) will provide an overview about the current status of OPEX in industry and will compare it to the very beginning when St.Gallen conducted its first Benchmarking exercise based on 2003 data. Additionally, they will also provide a deeper insight into the impact of OPEX tools and practices on performance based on statistical analysis. Calnan will then provide an overview about the advance in regulatory science and the impact this has on OPEX. This is followed by a description of the current pharmaceutical environment by Friedli and Bellm, looking as well on the on-going globalization as
on the changing economic landscape thus framing the context for the OPEX activities. Friedli and Bellm finalize the introductory part with a summary of the identified success factors for a sustainable implementation of Operational Excellence providing a bridge to parts B and C of the book.

Part II “Leading Operational Excellence – Outstanding Practices” brings together successful practices and interesting insights from the whole industry. Friedli and Werani start with an overview and introduction into this part. They are followed by Seller and Davis who describe the development of Pfizer’s Operational Excellence activities to one of the most sophisticated OPEX approaches in the industry. Kasper Mejlvang will then explain how Novo Nordisk succeeded in making its program to a brand not only inside of whole Novo Nordisk but also in the industry. cLEAN® became synonymous with succeeding in improving operations and had a direct impact of optimization programs beyond manufacturing. The following chapter belongs to Novartis. Steve Dreamer and Pav Niewiraowski will describe the latest progress Novartis has made in its aspirations to become a lean pharmaceutical manufacturer. Novartis currently leads the field in different innovative approaches to pharmaceutical manufacturing. Stark and Kumor will then give an insight into Abbott’s OPEX program. Highlighting how they used the former experiences from Abbott’s way to Operational Excellence. They relied on Class A activities as a base to form their very own unique approach to manage Operational Excellence. This is followed by a contribution of Troy Wright from Amgen, explaining how Amgen entered the journey to Operational Excellence and what the main guiding principles of this program are. Werani, Pfahlert, Reimers and Diederich proceed and share their insights in the challenges of an OPEX implementation at hameln pharma overcoming an initial focus on infrastructures to truly embrace people. Sanjit Lamba will then tell the readers the story of his plant in India. Built in record time and winning an award it is one of the leading examples for the potential of the Indian pharmaceutical industry. Morse, South and Walter will contribute their approach to help companies in “succeeding at the harder side of change”, drawing heavily from the rich experience of BCG in helping their customers on their way to Operational Excellence. This is followed by Friedli and Lembke who describe considerations about the optimal organizational structures to support excellence. This is followed by an update about the state-of-the-art in integrated product-process development in the industry delivered by Friedli and Ziegler. The idea to introduce already more stable production processes so as to avoid costly counter measures later in production is striking and has been successfully introduced in other industries before. However there are some pharma specifics that are against a fast realization of these benefits. Friedli, Mänder and Bellm will then deliver some guidance how to apply the right tools for specific problems. In a lot of excellence programs there is a focus on training people in specific tools but there is a lack of support in helping them to know when to apply what. This gap will be addressed by this contribution. Seller, Davis, Götzfried and Friedli will then introduce their work about plant complexity, the impact of complexity on performance and what OPEX can do to master complexity. Part II is concluded with some considerations about a structured management of