

Contents

Part I Introduction

1 Introduction to Leading Operational Excellence: Making OPEX a Competitive Weapon	3
Thomas Friedli and Prabir Basu	
2 OPEX: A Definition	7
Thomas Friedli and Daniel Bellm	
3 The History of OPEX in the Pharmaceutical Industry	27
Thomas Friedli and Jürgen Werani	
4 The Current State of Operational Excellence Implementation: 10 Years of Benchmarking	35
Thomas Friedli, Nikolaus Lembke, Uli Schneider, and Saskia Gütter	
5 Leading the Advance in Regulatory Science	59
Nuala Calnan	
6 A Look to the Environment and the Impact on OPEX	77
Thomas Friedli and Daniel Bellm	
7 Barriers and Success Factors in Managing Operational Excellence	103
Thomas Friedli and Daniel Bellm	

Part II Leading Operational Excellence: Outstanding Practices

8 From Process Stabilization to Plant Network Performance: Pfizer's Journey to Operational Excellence	117
Colin Seller and Richard Davis	
9 Ten Years with OPEX as a Brand: cLEAN® in Novo Nordisk Product Supply	131
Kasper Mejlvang	

10	Lean in Novartis Pharma: Sustainability Through a Five Step Deployment Methodology	145
	Steve Dreamer and Pav Niewiarowski	
11	Abbott Pharmaceuticals Journey of Business Excellence Standards	153
	Valentin Starke and Joseph Kumor	
12	Structuring and Implementing an Operational Excellence Program from Scratch in the Biotech Industry	169
	Wright Troy	
13	Implementing an OE Strategy on Plant Level	189
	Jürgen Werani, Volker Pfahler, Kai Reimers, and Gert Diederich	
14	Winning the “Facility of the Year” - Award with an Indian Plant . . .	209
	Sanjit Singh Lamba	
15	Succeeding at the ‘Harder’ Side of Change: The ‘ABCs’ of High-Performance Behavior	227
	Ned Morse, Nick South, and Gideon Walter	
16	Structures of Operational Excellence Initiatives	245
	Thomas Friedli and Nikolaus Lembke	
17	Preventive Process Stabilization by Integrated Process Development	263
	Thomas Friedli and Reto Ziegler	
18	Matching Problems with Tools	285
	Thomas Friedli, Christian Mänder, and Daniel Bellm	
19	Introducing Complexity in the Equation: How Pfizer Made Complexity on a Plant Level Transparent	323
	Colin Seller, Richard Davis, Matthias Götzfried, and Thomas Friedli	
20	Knowledge Exchange in Production Networks: Operational Excellence Multiplied	337
	Simone Thomas, Fabian Liebetrau, and Thomas Friedli	
 Part III Leading Operational Excellence: Outstanding Leadership		
21	Leadership Principles & Operational Excellence	347
	Thomas Friedli and Jürgen Werani	
22	Transformational Leadership - Shaping the Future of the Biopharmaceutical Industry	355
	Andy Crossman	

23 **Making Operational Excellence a Priority at Every Level** 369
David Hampton

24 **How Do We Create Leadership Pull for Operational Excellence? . . .** 385
Paul Docherty

25 **Leadership Characteristics for a Sustainable
OPEX-Implementation** 399
Uta Walkhoff

26 **Leading Operational Excellence in a Global Company** 411
Mark McColgan

27 **Leading an Operational Excellence Program at a Geographic
Area Level** 419
Jürgen Werani

28 **Continuous Improvement: A Path Towards Excellence** 433
Kim Sandell, Jesper Eriksson, Karin Eriksson, Maria Stigell Warnström,
and Kirsti Gjellan

Part IV Gaining the Future

29 **The Future of Pharmaceutical Manufacturing** 445
Prabir Basu, Thomas Friedli, and Daniel Bellm

30 **Managing Global Pharmaceutical Manufacturing Networks** 465
Thomas Friedli, Fabian Liebetrau, and Richard Luetzner

Appendix 487

About the Authors 513

Index 535