

Contents

Foreword ISPE (International Society for Pharmaceutical Engineering)	8
Foreword APV (International Association for Pharmaceutical Technology)	10
Section A – Introduction	
I The Pathway to Operational Excellence in the Pharmaceutical Industry – Overcoming the Internal Inertia	12
<i>Thomas Friedli, Prabir K. Basu, Thomas Gronauer, and Juergen Werani</i>	
II In Retrospect: A Summary of Operational Excellence in the Pharmaceutical Industry in 2006	18
<i>Thomas Friedli and Matthias Goetzfried</i>	
Section B – Starting Point of Our Journey	
Introduction	41
I Driving Forces Impacting Pharmaceutical Manufacturing and Supply	42
<i>Thomas Gronauer and Thomas Friedli</i>	
II Restoring the Balance: A Strategic Role for Operations	64
<i>Marc Herlant</i>	
III The Current State of Pharmaceutical Manufacturing – In Search of Science	77
<i>Prabir K. Basu</i>	
IV Examples of Technology-driven Operational Excellence Projects in Pharmaceutical Production Processes	82
<i>Guido Duennebier, Claus Riehle, and Hans Tups</i>	
V Operational Excellence Benchmarking – Quantifying the Advancements from 2004 to 2009	94
<i>Matthias Goetzfried, Thomas Friedli, and Saskia Guetter</i>	

Section C – Maps and Experiences

	Introduction	105
I	Building a Continuous Improvement Culture: Pfizer Moves Beyond "Right First Time"	106
	<i>Gerry Migliaccio, Nat Ricciardi, John Scott, and Norman Winskill</i>	
II	Wyeth Pharmaceuticals – Transforming Culture, Delivering Results – Exploring the Operational Excellence Productivity Frontier	120
	<i>Andy Crossman</i>	
III	The Best of Two Legacies: History, Present and Vision of the Roche-Genentech Operational Excellence Integration	
III.1	Genentech's Journey to Operational Excellence (2004-2009)	135
	<i>Colleen M. Griffith, Nick Rondoletto, and Fadel Hamed</i>	
III.2	Roche's Journey to OPEX (2005-2009)	144
	<i>Niklas Engler and Tilman Rock</i>	
III.3	OPEX in the Newly Integrated Roche PT Organization (2009 – today)	151
	<i>Colleen M. Griffith</i>	
IV	Delivering Operational Excellence in Technical Operations at Merck Serono	153
	<i>Pierre Caloz and Sven Wedemeyer</i>	
V	Operational Excellence in the Pharmaceutical Industry – the Case of Novartis	168
	<i>Steve Dreamer</i>	
VI	The Roadmap to Operational Excellence – Pattern and Elements of OPEX Programs	175
	<i>Thomas Gronauer, Thomas Friedli, and Matthias Goetzfried</i>	

Section D – Exploring the Landscape

	Introduction	201
I	A Model for the Sustainable Implementation of Operational Excellence	202
	<i>Thomas Friedli, Thomas Gronauer, and Juergen Werani</i>	
II	Making Operational Excellence Work – Training and Coaching Supporting Behavioral Change	220
	<i>Juergen Werani, Giusal Bellando-Randone, and Matthias Goetzfried</i>	
III	Operational Scorecard – Strategy Implementation	241
	<i>Paul Docherty</i>	

IV	Operational Excellence in Production Processes – A Consequence of Technology, Automation, and Integration <i>Claus Riehle</i>	255
V	Unlocking Potentials: A Value Stream Mapping Project <i>Juergen Werani, Thomas Friedli, and Matthias Goetzfried</i>	271
VI	Six Sigma Application: Successfully Integrating Suppliers into Operational Excellence Projects <i>Juergen Werani, Thomas Friedli, and Thomas Gronauer</i>	295
VII	Pfizer NEWCON: Bringing Operational Excellence to Life in a New Facility <i>Holger Weyhers and Georg Bernhard</i>	313
VIII	Continuous Manufacturing – Novartis-MIT Vision <i>Walter Bisson, Saskia Guetter, and Thomas Gronauer</i>	319

Section E – Redefining the Destination

	Introduction	323
I	The Future of Pharmaceutical Manufacturing: Quality by Design and Operational Excellence Reinforcing One Another <i>Prabir K. Basu</i>	324
II	The Future of Pharmaceutical Manufacturing: Towards Integrated Operational Excellence Programs and Continuous Improvement <i>Thomas Friedli and Thomas Gronauer</i>	330

Appendices

◦ Abbreviations	336
◦ Questionnaire	337
◦ Editors and Authors	356