

# CONTENTS

<b>CONTRIBUTORS</b>	<b>xiii</b>
<b>PREFACE</b>	<b>xxi</b>
<b>I SURVEYING AND MAPPING THE TERRITORY</b>	<b>1</b>
<b>1 Setting a Transformational Agenda</b>	<b>3</b>
1.1 Aims and Aspirations of the Book	3
1.2 Book Format	5
1.3 Intended Readership	6
1.4 A Book About Two Worlds in Contrast	8
1.5 The Pharmaceutical Lottery	8
1.6 Supply Chain Management in Context	17
1.7 The History of Supply and Value Generation	22
1.8 The Development of Processes to Manage the Supply Chain	24
1.9 Life in SCM	25
1.10 Moving Forward	26
<b>2 Plotting a Course to Patient Value</b>	<b>29</b>
2.1 Why Focus on Patient Value?	29
2.2 Where Does the Patient Currently Fit?	29
2.3 Why Is It Necessary to Plot a Course?	33
2.4 Understanding How the Course Is Presently Set	39
2.5 Capturing Value for Patients	42
<b>3 Pharmaceutical Drug Development</b>	<b>45</b>
3.1 Drug Development's Role in the Supply Chain	45
3.2 Introduction to Drug Development	47
3.3 The Medicinal Product	48
3.4 Clinical Trials	49
3.5 Related Development Programs	52
3.6 Managing Clinical Programs	57
3.7 Regulatory Affairs and Authorities	58

viii CONTENTS

3.8	Supply Chain Management in Development Programs	65
3.9	Manufacture and Supply of Commercial Products	68
3.10	Supply Chain Management for Commercial Products	69
<b>4</b>	<b>End-to-End Pharmaceutical Supply Chains</b>	<b>73</b>
4.1	Introduction	73
4.2	Where Does Responsibility for the Supply Chain Lay?	74
4.3	Sponsoring Companies, License Holders, and Their Supply Chains	75
4.4	Supply Chains for Small-Molecule Products	76
4.5	Starting at the Final Destination	78
4.6	How Drugs Enter the Body	78
4.7	Design of Drug Delivery Systems	79
4.8	What This Means for the Supply Chain	82
4.9	Key Aspects of GMP and GDP in Relation to SCM	82
4.10	Overview of the Stages on Route to Patient Delivery	86
4.11	Manufacture and Supply of Biological Entities	90
<b>5</b>	<b>Why Pharma Supply Chains Don't Perform</b>	<b>103</b>
5.1	Supply Chain Underperformance	103
5.2	Is There a Case to Answer?	103
5.3	Birth to Infancy: The Supply Chain Critical Stage	104
5.4	Commercial Supply Under the Patent Protection Umbrella	111
5.5	What This Means for the Pharmaceutical Supply Chain	116
<b>II</b>	<b>BUILDING A KNOWLEDGE FOUNDATION IN SCM</b>	<b>125</b>
<b>6</b>	<b>Supply Chain Management as a Competitive Weapon</b>	<b>127</b>
6.1	Competition and Business Strategy	127
6.2	The Marketing Mix	128
6.3	Porter's Five Forces	128
6.4	Porter's Generic Competitive Strategies	129
6.5	Porter's Value Chain	129
6.6	Competitive Strategy and Customers	133
6.7	The Japanese Experience	142
6.8	Total Quality Management	142
6.9	Lean Thinking	143
6.10	Focusing on Value for Money	146
6.11	SCM Processes in Competitive Strategy	148
6.12	SCM in Biotech and Virtual Companies	150
6.13	Competition in Pharmaceuticals	152

<b>7</b>	<b>Supply Chain Management Holistic</b>	<b>155</b>
7.1	The Relevance of SCM to Pharmaceuticals	155
7.2	Production Systems and the SCM Holistic	155
7.3	The Core of SCM	156
7.4	First Principle of SCM	156
7.5	Supply Chains as a Series of Interconnected Systems	158
7.6	Processes to Manage the Supply Chain	160
7.7	A Word About Processes	161
7.8	How the SCM Processes Should Mesh Together	163
7.9	Production and Inventory Control	163
7.10	Strategic Procurement	163
7.11	Transportation, Storage, and Distribution	164
7.12	Information Systems and Technology	164
7.13	Improvement	165
<b>8</b>	<b>Production and Inventory Control</b>	<b>167</b>
8.1	Core Mission	167
8.2	First Principles of Production and Inventory Control	167
8.3	The Wholesome Trinity in P&IC	174
8.4	The Wholesome Trinity and Customer Expectations	177
8.5	Leveraging the Wholesome Trinity	179
8.6	The Impact of Variety on Supply Chains	180
8.7	Designing Appropriate Production Systems	183
<b>9</b>	<b>Strategic Procurement</b>	<b>187</b>
9.1	Core Mission	187
9.2	The Purchasing Portfolio	188
9.3	The Process of Procurement	195
9.4	Strategic Sourcing and Planning	198
9.5	Outsourcing	201
9.6	Basic Principles in Contracting for Supply	206
9.7	Finally, Typical Organizational Tension over Procurement	213
<b>10</b>	<b>Transportation, Storage, and Distribution</b>	<b>215</b>
10.1	Defining the Core Mission	215
10.2	International Trade and Commerce	217
10.3	The World Trade Organization	217
10.4	Intermediary Arrangements	220
10.5	Terms of Trade: Incoterms	223
10.6	Ownership of Goods: Title	225
10.7	Third-Party Logistics Providers	226

<b>x</b>	<b>CONTENTS</b>	
	10.8 Customs	227
	10.9 Shipping Regulations Relating to Materials	229
	10.10 A Finishing Note	230
<b>11</b>	<b>Information Systems and Information Technology</b>	<b>233</b>
	11.1 Overview	233
	11.2 Brief Lay History of Computer Systems Development	234
	11.3 Important Perspectives on Information Systems	236
<b>12</b>	<b>Improvement</b>	<b>255</b>
	12.1 Why Improve?	255
	12.2 Improvement and Production Systems	257
	12.3 The Improvement Journey	258
<b>13</b>	<b>Bringing the Holistic Together</b>	<b>277</b>
	13.1 Setting the Scene	277
	13.2 The Process Explained	278
	13.3 Developing an Action Agenda	285
	13.4 Case Study	289
<b>III</b>	<b>PLANNING AND EXECUTING SUPPLY CHAIN CHANGE</b>	<b>293</b>
<b>14</b>	<b>Improvement in Pharmaceuticals</b>	<b>295</b>
	14.1 Where Are We Now?	295
	14.2 Subsequent Developments Since Inception	310
	14.3 A Blueprint for Quality by Design	311
<b>15</b>	<b>Exemplar Thinking in Organizational Improvement</b>	<b>335</b>
	15.1 Where Are We Now?	335
	15.2 What Is Meant by “Exemplar”?	338
	15.3 A Dialogue on Exemplar Improvement	338
	15.4 An Approach to SCM Based on Systems Thinking	357
<b>16</b>	<b>Building a Foundation for Sustainable Change</b>	<b>363</b>
	16.1 Focus on the Individual	363
	16.2 Individuals as Leaders	368
	16.3 Individuals as Motivators and the Motivated	370
	16.4 Individuals as Group Members	372
	16.5 Individuals as Participants in Cultural Change	376
	16.6 Case Study: Miles Ltd., Bridgend, Glamorgan	378

CONTENTS xi

<b>17 A Cure for the Pharmaceutical Supply Chain</b>	<b>395</b>
17.1 What Is the Disease State?	395
17.2 What Is the Label Claim for the Medicine?	396
17.3 What Will Life Hold Without the Medicine?	397
17.4 What Is This Better Way to Develop Drugs?	397
17.5 Full-Scale Production of Drugs	407
17.6 What Are the Barriers to Change?	410
17.7 What Are the Potential Benefits of Change?	413
17.8 Defining the Art of the Possible	414
17.9 Ending with the Beginning	417
<b>END NOTES</b>	<b>419</b>
<b>INDEX</b>	<b>429</b>

