

Contents

Part 1 – Introduction and St. Gallen QC Lab Work

1	QC – An Integral Part of Pharmaceutical Value Creation	
	<i>Thomas Friedli and Stephan Köhler</i> 12
1.1	Quality Issues 12
1.2	Quality Control – An Integral Part of the Quality System 12
1.3	Operational Excellence in Quality Control 13
1.4	Objective and Structure of the Book 14
2	Leading the Transformation from Compliance to Excellence in QC	
	<i>Nuala Calnan</i> 16
2.1	From Evolution to Revolution 16
2.2	What Does This Revolution Mean for the QC Labs of the Future? 17
2.3	Transformation through Digitalization 19
3	Measuring What Matters: Shifting the Emphasis from Transactional Cost-based Budgeting to Value-Chain Excellence in QC	
	<i>Nuala Calnan</i> 21
3.1	The Evolving QC Lab Landscape 21
3.2	Understanding the Cost of Quality Concept 22
3.3	The Normalization of Deviance 24
3.4	Understanding the <i>Value</i> of Measuring Cost of Quality 25
4	St. Gallen Quality Control Lab Operational Excellence	
	<i>Stephan Köhler</i> 27
4.1	St. Gallen QC Lab Operational Excellence Benchmarking 27
4.2	Current State in QC: Performance and Enabler Implementation 36
4.3	Industry Exchange – QC Lab Exchange Platform 42

Part 2 – QC Context and In-depth Analysis

5	Quality Control in the Context of FDA Quality Metrics	
	<i>Thomas Friedli and Marten Ritz</i> 48
5.1	FDA Quality Metrics Initiative 48

5.2	Pharmaceutical Production System Model	49
5.3	St. Gallen FDA Quality Metrics Research Findings	54
5.4	Quality Culture in QC Labs	56

6	Performance Patterns in Quality Control Labs		
	<i>Stephan Köhler</i>	60
6.1	Research Approach	60
6.2	Performance Measurement Model in QC Labs	61
6.3	Operating Context and QC Lab Effectiveness Relation	65
6.4	QC Lab Effectiveness and Enabler Relation	68
6.5	Application of Performance Measurement Model	73
6.6	Conclusion	84

Part 3 – Practitioner Contributions

7	Overview on Focus Topics in Chapters of Part 3		
	<i>Thomas Friedli and Stephan Köhler</i>	90

8	ISPE GAMP – Building Data Integrity into Lab Working Practices		
	<i>Charlie Wakeham, Mark Newton, and Heather Longden</i>	92
8.1	Introduction	92
8.2	Examples of Current Data Integrity Challenges in QC Laboratories	92
8.3	Laboratory Systems as a Source of Data Integrity Risks	94
8.4	Data Integrity by Design	99

9	PDA – Maintaining Data Integrity in Pharmaceutical Laboratories		
	<i>Denyse Baker</i>	110
9.1	Good Decisions Rely on Good Data	110
9.2	Health Authority Expectations and Key Principles	111
9.3	Challenges with Computerized and Hybrid Systems	113
9.4	Health Authority Response and New Guidance	114
9.5	Recommended Basic Controls in Analytical Laboratories	115
9.6	Recommended Basic Controls in Microbiological Laboratories	116
9.7	Risk-Based Approach to Management of Data Integrity in the Laboratory	117
9.8	Consideration of Human Factors and Culture	119
9.9	Remediation of Data Integrity Issues	121
9.10	Conclusion	121

10 Eli Lilly – Creating a Culture of Operational Excellence in Pharmaceutical QC Labs	
<i>Jacqueline Larew</i> 124
10.1 Introduction 124
10.2 Operational Excellence in the QC Lab – Why now? 124
10.3 A Culture of Operational Excellence – What does it mean? 125
10.4 Creating a Culture of Operational Excellence – What does it take? 126
10.5 Beware of the Watch Outs 130
 11 Amgen – How We Successfully Applied Lean in the QC Labs	
<i>Dan Latham-Timmons, Patrick Conneran, and Julie Nielson</i> 132
11.1 Introduction and Background 132
11.2 Unique Features of Biopharma QC Labs 133
11.3 Our New Framework 134
11.4 Concept Design Phase 135
11.5 Detailed Design Phase 137
11.6 Updating the Daily Management System 140
11.7 Examples of Successes 141
11.8 Examples of Failures 142
11.9 Obstacles Encountered 143
11.10 Next Steps 143
11.11 Signs of Slippage 144
11.12 Key Points to Keep in Mind 144
11.13 Conclusion 145
 12 Meocon – Busy People, Lazy Samples	
<i>Fabio Oro and Thomas Gerber</i> 146
12.1 Introduction 146
12.2 What to Expect? 147
12.3 Key Pillars – What Really Matters When Doing Improvement Projects in QC Labs 148
12.4 A Typical Lab Today 149
12.5 Lab Dynamics 150
12.6 Improvement Roadmap 153
12.7 Launch Project & Evaluation 155
12.8 Diagnosis & Synthesis 160
12.9 Implementation through Prototyping 165
12.10 Learnings 173
12.11 Conclusion 173

13 Knowledge Excellence in the Lab: How Knowledge Management Can Enhance Lab Performance

Martin Lipa, Paige Kane, and Anne Greene 174

13.1 Introduction 174

13.2 Knowledge Management in the Biopharmaceutical Industry 174

13.3 Managing Knowledge in the QC Laboratory 176

13.4 Technology Transfer: A Common yet Underappreciated Knowledge Transfer Activity 177

13.5 Current State of Knowledge Transfer as Part of Technology Transfer 178

13.6 What Next: Understanding the Problem and What to Do About it 179

13.7 What Makes a Good KM Solution? 180

13.8 Possible KM Approaches to Improve AMT – and the QC Laboratory at Large 182

13.9 Author Perspectives: Relating Knowledge Management to Quality Culture and Digital Transformation 183

13.10 Conclusion 184

14 Merck KGaA – Use of DMAIC to Deliver Value in Biotech QC Labs

Martina Bigoli, Simone Bego, Giuseppe Viola, Andrea Taiani, Abhijeet Satwekar, and Gabriella Angiuoni 186

14.1 Operational Excellence Laboratory Transformation 186

14.2 Utilizing the Lean Sigma Methodology to Improve Chromatographic Workflow 186

14.3 Define Phase: Focus on Problem & Project Goals 187

14.4 Measure Phase: Setting the Baseline and the As-Is Process 190

14.5 Analyze Phase: Identifying the Main Root Causes 192

14.6 Improve Phase: Making the Change Happen 194

14.7 Control Phase: Sustaining the Improvements 197

14.8 Conclusion and Lesson Learned 198

15 Merck KGaA – Life Cycle Management of Analytical Methods

Sabrina Palumbo 200

15.1 Need for LCM of Analytical Methods 200

15.2 Prospective LCM 201

15.3 Reactive LCM 202

15.4 Merck KGaA History of LCM of Analytical Methods Group 203

16 Novartis – Digital QC Laboratory Transformation

Thomas Groeschner 208

16.1 Digital Transformation 208

16.2 Business Case 211

16.3	Digital Execution	213
16.4	Sustainability	216
17	Accenture – Standard Work: The Fundamental Digit of the Digital Lean Lab		
	<i>Lorcán Mannion and Alan Maloney</i>	217
17.1	Introduction	217
17.2	QC Standard Work and the Lean Lab	218
17.3	Digital Transformation of the QC Lab	223
17.4	Conclusion	229
18	BioPharm Excel – Establishing a Culture of Excellence in your QC Operations		
	<i>Nuala Calnan</i>	230
18.1	Understanding the Why!	230
18.2	Cultural Excellence: Performance through People	230
18.3	Speak Up	231
18.4	When Building a Learning Culture Behaviors Matter!	231
18.5	Shifting Mindsets from Reactive to Proactive	233
18.6	Conclusion	234
Part 4 – Summary			
19	Key Messages of this Book		
	<i>Thomas Friedli and Stephan Köhler</i>	236
	Editors' CVs	240
	Authors' Addresses	242
	Acronyms	244
	Index	246