Contents

Foreword iii
Author Acknowledgments v

Chapter 1: Driving Successful Commercial Product Launches 1
Flora Sandra Siami, MPH

Chapter 2: Elements to Consider When Developing a Global Regulatory Strategy 13
Thomas Hutchinson, MS, CQA, CMDA, CMQ/OE, RAC-US, FRAPS

Chapter 3: Core Development Teams 19
Anuja Yardi, MS-RA, MSPM, MPharm, RAC–US

Chapter 4: Components of Regulatory Strategy – The Basics 47
Melissa Walker, MS, RAC-US, FRAPS

Chapter 5: Setting up a Quality Management System 59
Susumu Nozawa, RAC-EU, RAC-US, FRAPS

Chapter 6: Risk Management Strategies for Device Design and Development Processes 83
Shannon Hoste, MSM, MSSE

Chapter 7: Global Medical Device Labeling Strategies 99
Foram Shukla, PharmD, MS-RA

Chapter 8: Manufacturing 115
Andrea Armando, MS

Chapter 9: Nonclinical Laboratory Testing 123
Dorota Grabowska, PhD, and Peter A. Takes, PhD, RAC-US, FRAPS

Chapter 10: Global Medical Device Clinical Strategy 135
Dawn N. Norman, MS

Chapter 11: In Vitro Diagnostic Medical Devices 143
Jocelyn Jennings, MSRA, RAC-Devices, RAC-Drugs, RAC-US, RAC-Global, FRAPS

Chapter 12: Combination Products 155
Allyson B. Mullen, JD

Chapter 13: Global Regulatory Processes 165
Manuel Urena, Xianjun Chen, MS; and Brian Young

Chapter 14: Global Regulatory Process – Third-Party Point of View 179
Gert Bos, PhD, MSc, FRAPS

Purchased from RAPS Library (library.raps.org) for the exclusive use of unknown.
© 2026 RAPS Library. Please report unauthorized use to raps@raps.org

Chapter 15: Use of Standards in Medical Device Global Regulatory Strategy 187
Susumu Nozawa, RAC-EU, RAC-US, FRAPS

Chapter 16: Global Medical Device Marketing Strategy 207
Charles Tam, MBA, EP

Chapter 17: Regulatory Resources for Strategy Development 225
Gretchen E. Parker, PhD, CIP, RAC-US

Chapter 18: Global Postmarketing Regulatory Strategy 249
Scott D. Dickerhoff, MBA, and Samata Veluvolu, MBA, RAC-US

Chapter 19: Borderline Regulation of Stem Cell Technologies: Therapies, Devices, and Combination Products 275
Beat U. Steffen, MSc, MBA, RAC-Devices, FRAPS, and Andrea Lopes, PhD

Chapter 20: Patents and Intellectual Property 287
Stanley F. Chalvire, PharmD, JD, and Sean D. Detweiler, JD

Chapter 21: Software 299
Philip Desjardins, JD

Chapter 22: Cybersecurity 309
Colin Morgan, MS, CISSP, CISM

Index 321

Figures

Figure 1-1. Market Access External Stakeholders 2
Figure 1-2. PDP Internal Stakeholders and Collaborators 3
Figure 1-3. Reimbursement for Medical Devices 6
Figure 4-1. Comparison of Target Market Release Timelines 55
Figure 5-1. Basic Process Model 61
Figure 5-2. PDCA Cycle in Resource Management 61
Figure 5-3. Implementing an ISO 13485:2016 QMS 65
Figure 5-4. Sample Schedule for QMS Implementation 67
Figure 5-5. QMS Documentation Defining Responsibilities 68
Figure 5-6. Typical QMS Document Hierarchy 69
Figure 5-7. Iterative PDCA Cycle 70
Figure 5-8. ISO 17021 QMS Certification Cycle 72
Figure 5-9. Design Process 77
Figure 6-1. Framework Developed by the Presidential Commission 1997 Report 85
Figure 6-2. NIST Cybersecurity Framework 2.0 Governance is Designed to be a Cross-Cutting Function to Inform and be Infused throughout the Other Five Elements.[12] 86
Figure 6-3. NIST AI RMF Governance is Designed to be a Cross-Cutting Function to Inform and be Infused throughout the Other Three Elements 87
Figure 6-4. High-Level Summary of Some Key Steps in Product Risk Management 90
Figure 6-5. Comparison Example of Top-Down Hazard Analysis and Bottom-Up FMEA Tools. 92
Figure 7-2. Example of a Medical Device Label for Use in Multiple Regions 102
Figure 9-1. Strategy for Performing Animal Studies 129
Figure 15-1. Document Hierarchy 192
Figure 21-1. Rule 11 of Annex VIII of EU MDR 306
Figure 22-1. Product Security Framework From the JSP 311
Figure 22-2. AAMI TIR57 and ISO14971 Crosswalk 313

Purchased from RAPS Library (library.raps.org) for the exclusive use of unknown.
© 2026 RAPS Library. Please report unauthorized use to raps@raps.org

Tables

Table 1-1. Main Type of Coding in the US Healthcare Reimbursement System 8
Table 3-1. Example Development Phases 24
Table 3-2. Regulatory Pathway Assessment Elements 36
Table 3-3. Regulatory Strategy and Plan Elements 37
Table 3-4. Ebb and Flow of Core Team Member Involvement 42
Table 4-1. GRS Simplified Element Table 48
Table 4-2. Regulatory History Considerations 51
Table 4-3. Tools or Treatment 52
Table 4-4. Expanded Example of the GRS Element Table 56
Table 4-5. Regulatory Submission Requirements 57
Table 4-6. Summary of Regulatory Risks 57
Table 5-1. Key Differences Between ISO 9001 and ISO 13485 59
Table 5-2. Similarities Between ISO 9001 and ISO 13485 60
Table 5-3. Applicability of ISO 13485 in Various Global Jurisdictions 64
Table 5-4. Benefits and Barriers to Certification 71
Table 5-5. Certification Body QMS Assessment Objectives, Scope, and Criteria 72
Table 5-6. Audit Duration for Medical Device ISO 13485 Audits Based on Staff Numbers 73
Table 5-7. Factors That May Increase or Reduce Audit Durations 73
Table 6-1. Project Risk Mitigation Strategies 88
Table 6-2. Overview of Tools Used within Risk Management 91
Table 6-3. IMDRF Code Mapping to ISO 14971 95
Table 7-1. Comparison of Terminology "Label vs. labeling" in the US and EU 100
Table 7-2. Key Medical Device Labeling Regulations in the US: Code of Federal Regulations 100
Table 7-3. Key Medical Device Labeling Regulations in the EU MDR 102
Table 7-4. ISO FDIS 20417: Medical Devices—Information to be Supplied by the Manufacturer 103
Table 9-1. The Universal Elements of GLP 124
Table 9-2. Examples of GLP Violations From FDA Warning Letters 125
Table 9-3. Sources of Device Risk 126
Table 9-4. Biocompatibility Tests 127
Table 9-5. Medical Device Classification Based on the Nature of Body Contact and Contact Duration 128
Table 9-6. Basic Animal Study Protocol Elements 128
Table 9-7. Animal Models for In Vivo Medical Device Assessment 130
Table 9-8. International Animal Research Laws, Policies and Guidelines 131
Table 9-9. Useful Web Resources for Planning and Conducting Animal Studies in Accordance with Three Rs Principles 131
Table 9-10. Questions a Company Should Consider When Selecting a CRO 132
Table 16-1. Example of a CV Medical Device Company Product Development Matrix 208
Table 16-2. Country-Specific Information from the Handbook of Pharma and MedTech Compliance 214
Table 16-3. High-Level Marketing and Advertising Information for Countries in Asia-Pacific 215
Table 16-4. High-Level Marketing and Advertising Information for Countries in Europe 216
Table 16-5. High-Level Marketing and Advertising Information for Countries in Latin America and South America 217
Table 17-1. African and Middle Eastern Regulatory Agencies 229
Table 17-2. Asia/Pacific Regulatory Agencies 231
Table 17-3. European National Competent Authorities 232
Table 17-4. Eastern European Agencies 233
Table 17-5. Latin American Regulatory Agencies 234
Table 17-6. North American Regulatory Agencies 234
Table 17-7. Global Regulatory Professional Trade Organizations 236
Table 17-8. Miscellaneous Resources 240
Table 17-9. African/Middle Eastern Intelligence Resources 242
Table 17-10. Asia/Pacific Intelligence Resources 242
Table 17-11. European Intelligence Resources 242
Table 17-12. Latin American Intelligence Resources 243

Purchased from RAPS Library (library.raps.org) for the exclusive use of unknown.
© 2026 RAPS Library. Please report unauthorized use to raps@raps.org

Table 17-13. North American and Other Critical Intelligence Resources 244
Table 19-1. Summary of Select Revenue-Generating Cell Therapy Products Currently on the Market 276
Table 19-2. Definitions of Manipulations Considered Minimal (US) or Not Substantial (EU) 277
Table 19-3. Summary of Regulatory Routes and Documents Applicable to Stem Cell and/or Device Products 278
Table 21-1. IMDRF SaMD Categories 301
Table 21-2. IMDRF Clinical Evaluation Process 302

Regulatory Affairs Professionals Society
Purchased from RAPS Library (library.raps.org) for the exclusive use of unknown.
© 2026 RAPS Library. Please report unauthorized use to raps@raps.org

1

Driving Successful Commercial Product Launches

Flora Sandra Siami, MPH

Introduction

In 2025, the global medical device market was valued at roughly $570 billion and estimated to reach $1 trillion by 2034.[1] According to AdvaMed, at 40%, the United States (US) holds the largest percentage of the global medical device market.[2] Companies can no longer rely solely on regulatory market authorization for their products to be competitive, as their commercial success requires pricing, reimbursement, and market adoption.

However, these elements become challenging as the healthcare delivery model continues to transform owing to continued uncontrollable cost increases, higher healthcare utilization, and increased regulatory scrutiny. Purchasing decisions have been transferred from clinical decision-makers to economic buyers. Payment models have reassigned financial risk from payers (e.g., Fee-for-Service [FSS]) to providers (e.g., Value-Based Care). Therefore, healthcare providers are focused more than ever on controlling costs, being more efficient, and delivering improved patient care.

As these foundational shifts in the healthcare system continue, medical device companies must step out of their traditional role and evolve, focusing on solutions that reduce the cost of care, increase efficiencies, and improve patient outcomes by leveraging data and building intelligence into their products as essential parts of the new device value proposition to the multiple stakeholders within the healthcare delivery system.[3] A stakeholder's willingness to pay for a medical device will be tied to its impact on patient outcomes, cost-effectiveness, and support for quality-based performance metrics.

Companies, more than ever, need to understand the fluctuating landscape for successful commercial device launches. This chapter provides readers, especially those responsible for developing and building a regulatory strategy, with a framework to achieve a successful commercial product launch. Regulatory leaders and leaders from other cross-functional departments must recognize that their strategies and tactics should not be viewed from their perspective alone. Instead, they must understand that they are part of a process that has a patient-centered and market adoption end in mind. To thrive in this transforming healthcare environment, a collaborative cross-functional market access approach must be embraced by everyone in the organization. While a considerable portion of this Chapter discusses the US reimbursement landscape since it is the most complex, the European Union (EU) and other global markets are considered.

Commercialization Through Cross-Functional Collaboration With Market Access Mindset

In the past, when it came to Product Development Plans (PDPs), most medical device manufacturers either rarely considered payment, value, or their end users or only considered some of these factors during product launch. However, in recent years, medical

Purchased from RAPS Library (library.raps.org) for the exclusive use of unknown.
© 2026 RAPS Library. Please report unauthorized use to raps@raps.org