

Contents

Chapter 1	An Overview of Medical and Regulatory Writing..... <i>By Danny A. Benau, MSOD, PhD</i>	1
Chapter 2	Good Documentation Practices	15
	<i>By Jenny Grodberg, PhD, RAC, Jocelyn Jennings, MS, RAC, and Joanne Rupprecht, Esq, RAC</i>	
Chapter 3	General Considerations for Quality Regulatory Writing..... <i>By E. Mitchell Seymour, PhD, RAC and Gert Bos, MSc, PhD, FRAPS</i>	23
Chapter 4	Guidance Documents: Beyond the Code of Federal Regulations	29
	<i>By Lisa DeTora, PhD, Jenny Boyar, PhD, Robin Martin, MBA, and Jenny Grodberg, PhD, RAC</i>	
Chapter 5	Medical Device Submission Considerations Beyond the US, Canada, and EU..... <i>By Jenny Boyar, PhD and Robin Martin, MBA</i>	41
Chapter 6	Developing Standard Operating Procedures and Planning and Strategy Documents	45
	<i>By Mariam Aslam</i>	
Chapter 7	Review and Approval Process..... <i>By Jocelyn Jennings, MS, RAC</i>	57
Chapter 8	Clinical Trial Protocols..... <i>By Sharanya Ramasubramanian, MS and Jenny Chen, MD, PhD, RAC</i>	71
Chapter 9	Informed Consent Form Preparation	79
	<i>By Jenny Grodberg, PhD, RAC</i>	
Chapter 10	Data Analysis Plans	89
	<i>By Lisa DeTora, PhD</i>	
Chapter 11	Clinical Study Reports	99
	<i>By Brooke Diorio, John M. Ellison, MS, Helle-Mai Gawrylewski, Anna Mendlin, PhD, Bertil Wagner, and Kathy Wekselman, PhD, RN</i>	
Chapter 12	Integrated CMC Documentation	111
	<i>By Mariam Aslam</i>	
Chapter 13	Integrated Nonclinical Documentation..... <i>By Lisa DeTora, PhD</i>	115

Chapter 14	Integrated Clinical Documentation	125
	<i>By Lisa DeTora, PhD and Danny A. Benau, MSOD, PhD</i>	
Chapter 15	Investigator's Brochure.....	145
	<i>By Deborah Leonard, RN, MS</i>	
Chapter 16	Labeling	151
	<i>By Tina O'Brien, MS, RAC</i>	
Chapter 17	Background Packages.....	159
	<i>By Jocelyn Jennings, MS, RAC</i>	
Chapter 18	Responses to Questions or Requests for Information	171
	<i>By Nathalie Innocent, MS, RAC</i>	
Chapter 19	Interdisciplinary Document, Dossier Maintenance.....	179
	<i>By Evelyn De La Vega Stewart, MSc, RAC</i>	
Chapter 20	Value Dossiers	185
	<i>By E. Mitchell Seymour, PhD, RAC, Kayla Ambroziak, PharmD, and Gert Bos, MSc, PhD, FRAPS</i>	
Chapter 21	Vaccines and Biologics	189
	<i>By Lisa DeTora, PhD</i>	
Chapter 22	Biosimilars: Special Considerations	203
	<i>By Monica Ramchandani, MS, PhD</i>	
Chapter 23	Combination Product Design and Development	215
	<i>By Jiaying Shen, PhD</i>	
Chapter 24	Rare Diseases—Special Considerations for Orphan Designations	225
	<i>By Beth Silverstein, MS, RAC and Jocelyn Jennings, MS, RAC</i>	
Chapter 25	Pediatric Investigational Plan (PIP).....	237
	<i>By Jocelyn Jennings, MS, RAC</i>	
Chapter 26	Accelerated Filings.....	245
	<i>By Joanne Rupprecht, Esq, RAC and Siegfried Schmitt, PhD</i>	
Chapter 27	Publications.....	253
	<i>By Eileen M. Girten, MS</i>	
Chapter 28	Literature Reviews	259
	<i>By Michelle Carey, PhD</i>	
Chapter 29	Lay Summaries of Clinical Study Results	265
	<i>By Thomas M. Schindler, PhD</i>	
Chapter 30	Future Directions for Regulatory Writing.....	277
	<i>By Steve Carr and Helle Gawrylewski</i>	

Figures

Figure 6-1.	Example Template Guide to Preparing Planning and Strategy Document for Regulatory Submission	48
Figure 6-2.	Example SOP Template	52
Figure 6-3.	Example Template Flow Diagram	53
Figure 6-4.	Example Template of Work Instruction	54
Figure 7-1.	Initial Marketing Authorisation Application Through the Centralised Procedure	68
Figure 11-1.	Flowchart for Developing CSRs	103
Figure 16-1.	Labeling Examples	152
Figure 18-1.	Example of Agency Deficiency Communication	175
Figure 22-1.	Stepwise Process for Biosimilarity Demonstration	207
Figure 26-1.	Advances in the Discovery and Development of Orphan Drugs Over the Past Four Decades	250
Figure 26-2.	China National Medical Products Administration (NMPA) Emergency Approval Process and Timeline for Drug Products	251
Figure 29-1.	Example of a Lay Summary for Children	273

Tables

Table 1-1.	Definitions of Medical Writer	2
Table 1-2.	Summary of Prescription Drug User Fee Act (PDUFA) and its Reauthorizations	8
Table 4-1.	Overview of Selected FDA COVID-19-Related Guidance Documents	32
Table 4-2.	Regulatory Requirements for Medical Devices	33
Table 4-3.	Overview of ICH Quality Guidelines	34
Table 4-4.	Overview of ICH Safety Guidelines	36
Table 4-5.	Overview of ICH Efficacy Guidelines	37
Table 4-6.	Overview of ICH Multidisciplinary Guidelines	39
Table 7-1.	Review Milestones	61
Table 7-2.	Timetable for Evaluation of the MAA via the Centralised Procedure	66
Table 9-1.	Selected Historical Events in Human Experimentation	80
Table 9-2.	Essential Informed Consent Form Elements	81
Table 9-3.	Additional Informed Consent Form Elements	82
Table 9-4.	Examples of Lay Language	84
Table 9-5.	Sample GDPR Privacy Notice Elements for Informed Consent Form	86
Table 10-1.	Guidelines Specifically Referenced in ICH Statistical Principles for Clinical Trials E9	92
Table 11-1.	Guidance Documents for CSRs	100
Table 11-2.	Common Terminology for CSRs	101
Table 12-1.	Example Template of Section 3.2.P.3 Manufacture and 3.2.P.3.1 Manufacturer(s)	112
Table 13-1.	US FDA Nonclinical Testing Guidance Documents	116
Table 13-2.	Content Areas of the Three Nonclinical Written Summaries	119
Table 14-1.	Documents That May Contain an Integrated Discussion of Clinical Data	130
Table 14-2.	Clinical Overview Goals	132
Table 14-3.	Clinical Overview Text Sections as Described in ICH M4E With Brief Explanations	133
Table 14-4.	Summary of New Guidance on Clinical Overview Section 2.5.6 Benefit-Risk Conclusions (Text Sections)	135
Table 14-5.	Clinical Summary Text Subsections	136
Table 14-6.	ICH M4E Table Templates for Clinical Summary Subsections	137
Table 14-7.	ICH E2C Contents of the Periodic Safety Update Report	141
Table 15-1.	Investigator's Brochure Contents Specified in ICH E6, Section 7	147

Table 16-1.	User Profile Examples	153
Table 16-2.	Common Labeling Elements.....	155
Table 16-3.	Labeling Risk Category Statements	156
Table 17-1.	FDA Meeting Types and Deadlines	161
Table 17-2.	Tips for Formulating Questions	162
Table 17-3.	Sponsor/Applicant-Areas That may Lead to Questions	164
Table 17-4.	510(k) Submission Questions	167
Table 17-5.	PMA Submission Questions	168
Table 19-1.	IDE Annual Report Contents	182
Table 19-2.	PMA Annual Report Contents	182
Table 19-3.	IND Annual Report Contents.....	182
Table 19-4.	ANDA/NDA Annual Report Contents.....	182
Table 20-1.	AMCP Format	187
Table 20-2.	Comparison of AMCP Dossier and International HTA.....	187
Table 20-3.	Team Members and Their Responsibilities	188
Table 21-1.	Some Current US Biological Product Definitions.....	191
Table 21-2.	EMA Biologics Definitions	192
Table 21-3.	US Biologics Regulation (1902–2020) Selected Important Developments	194
Table 21-4.	Division of Products Between CDER and CBER Under the 1991 Intercenter Agreement ...	196
Table 22-1.	Approved Biosimilars in the US	204
Table 22-2.	Differences in Regulatory Requirements for Reference Products, Generics, and Biosimilars	206
Table 24-1.	Available Resources.....	232
Table 25-1.	Pediatric Population.....	238
Table 25-2.	PIP Submission Process.....	241
Table 26-1.	Comparison of Expedited Programs for Serious Conditions.....	247
Table 26-2.	EMA Accelerated Marketing Authorisation Pathways.....	250
Table 27-1.	Common Publication Deliverables	254
Table 27-2.	Differences Between Regulatory and Publications Writing.....	255
Table 27-3.	Transparency Initiatives Affecting Publications Writing	256
Table 28-1.	Narrative Versus Systematic Reviews.....	260
Table 28-2.	Examples of Electronic Information Sources.....	261
Table 29-1.	Content of Lay Summaries According to Annex V of EU CTR	267
Table 29-2.	Summary of the European Expert Group Recommendations for Structuring a Lay Summary	268
Table 29-3.	MRCT Guidance on Timing of Information on Lay Summaries.....	269
Table 29-4.	Comparison of EU Clinical Trial Regulation and Expert Group Recommendations With MRCT Guidance.....	270