# Contents

Preface – Pharmacovigilance Medical Writing Comes of Age ix  
Acknowledgements xiii  
Abbreviations xv  

1 Pharmacovigilance Medical Writing – An Overview Across the Drug Development Process 1  
2 Pharmacovigilance Medical Writing for Clinical Trials 5  
  2.1 Introduction 5  
  2.2 The EU Annual Safety Report and US IND Annual Report – A Historical Look at Reporting from Clinical Studies 6  
  2.3 The Development Safety Update Report 9  
  2.4 References 30  
3 Pharmacovigilance Medical Writing for Marketing Authorization 33  
  3.1 Introduction 33  
  3.2 The Summary of Clinical Safety 34  
  3.3 The Integrated Summary of Safety 60  
  3.4 The 120-Day Safety Update Report 73  
  3.5 References 74  
4 Pharmacovigilance Medical Writing in Risk Evaluation and Management 75  
  4.1 Introduction 75  
  4.2 The EU Risk Management Plan 76  
  4.3 The Risk Evaluation and Mitigation Strategies Report 96  
  4.4 The Benefit-Risk Evaluation Report 106  
  4.5 References 114  
5 Pharmacovigilance Medical Writing for Marketed Products 117  
  5.1 Introduction 117  
  5.2 The EU Periodic Safety Update Report 119  
  5.3 The US Periodic Adverse Drug Experience Report 147  
  5.4 The PSUR Addendum Report 157
vi Contents

5.5 The Summary Bridging Report 163
5.6 References 169

6 The Ad-Hoc Safety Review and Response to Questions Document 171
6.1 Introduction 171
6.2 The Ad-Hoc Safety Review 172
6.3 The Response to Questions Document 179

7 The Rest of the World 185
7.1 Introduction 185
7.2 Japan 186
7.3 Canada 188
7.4 Australia and New Zealand 188
7.5 India 189
7.6 Singapore and Taiwan 190
7.7 References 191

Appendices
Appendix 1: Sample Line Listing 193
Appendix 2: Sample Summary Tabulation 197
Appendix 3: Another Look at the US IND Annual Report 199
Appendix 4: The New Pharmacovigilance Legislation in the EU 211
Appendix 5: The New EU Risk Management Plan 215

Glossary 253

Index 259