Author Acknowledgments

The Regulatory Affairs Professionals Society (RAPS) would like to express appreciation to the following subject matter experts who shared their experience and knowledge and volunteered their time by contributing to this book. RAPS also would like to recognize Meredith Brown-Tuttle whose work on both the first and second editions laid the groundwork for this third edition.

Daanish Ashraf, PharmD

Regulatory Intelligence Lead Biogen US

James Biddlecombe

Senior Consultant Deloitte LLP

Gert Bos, MSc, PhD, FRAPS

Executive Director and Partner Qserve Consultancy BV Netherlands

Linda Bowen, MSc, RAC, FRAPS

Head of Regulatory Policy and Intelligence Seagen US

George Cusatis MS, RAC

Director Merck and Co., Inc. US

Reid D'Amico, PhD

Specialist Senior Deloitte Advisory US

João Duarte, MPharm

Director, Chief of Staff and Head of Regulatory Intelligence and Policy Global Regulatory Affairs Alexion Pharmaceuticals France

Malka Fraiman, MSC

Specialist Master Deloitte & Touche LLP US

Mayura Gill

Manager Deloitte & Touche LLP US

Jessica Hale, PharmD

Senior Specialist Devices and Digital Health Merck & Co., Inc. US

David Husman, PhD, ASQ CPGP, RAC

President and Principal Consultant David Husman Consulting US

Robert Kester, MS

Senior Director, Global Regulatory Affairs Oncology and In-Vitro Diagnostics Group Merck & Co., Inc. US

Susan Laufer, MSc

Senior Consultant Parexel International US

Andrew Leung, PharmD

Regulatory Scientist Assistant Devices and Digital Health Merck & Co., Inc. US

Kirsten Messmer, PhD, RAC

Principal Regulatory Affairs Specialist Regulatory Affairs PPD US

Jason Moore, MS, MBA, RAC

Associate Vice President, Regulatory Affairs Reata Pharmaceuticals, Inc. US

Anne Vinther Morant, PhD, MSc

Regulatory Science Consultant Anne Morant Consulting Denmark

Mary Nteris, PhD, GAICD

Director and Consultant Enimera RegsPlus Australia

Darin Oppenheimer DRSc, RAC, PMP

Senior Director, Regulatory Affairs US Medtronic US

Suraj Ramachandran MS, RAC

Director of Regulatory Affairs Devices and Digital Health Merck & Co., Inc. US

Elina Sarmah, MS

Senior Consultant Deloitte & Touche LLP US

Charity-Anne M. Schuller, PharmD, MS, RAC

Senior Director PPD US

Céline Rodier Seguy, PharmD, DES

Senior Research Analyst Centre for Innovation in Regulatory Science (CIRS) Clarivate France

Siegfried Schmitt, PhD

Vice President Technical Parexel UK

William K. Sietsema, PhD

Vice President, Global Regulatory Affairs Caladrius Biosciences US

Colin Spence

Consultant
Deloitte Consulting LLP
US

Oliver Steck

Principal Deloitte & Touche LLP US

Charles Tam, MBA

Senior Manager, Regulatory Affairs Edwards Lifesciences (Canada) Inc. Canada

Kristin Van Goor, PhD

Senior Director Head of North America Regulatory Policy and Intelligence Vertex Pharmaceuticals US

Michael Vivion, PhD

Principal ECG Healthcare US