

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.

EDITOR

**Linda Bowen, MS, RAC-CAN,
RAC-EU, RAC-US, FRAPS**
Adjunct Professor
Temple University Pharmacy School

AUTHORS

Lieselotte L. Bloss, DVM
Senior Consultant, Regulatory Affairs;
Managing Partner
The Bracken Group

Kenneth G. Butz, MS
Director, Regulatory Affairs, Medical
Devices and Diagnostics
PPD clinical research business of
Thermo Fisher Scientific

Tony E. Catka, PhD
Director, Regulatory Intelligence
Ionis Pharmaceuticals, Inc.

James Lindsay Cobbs, RPh
Principal & Senior Policy Advisor
Apath Nexus Consulting

Virginia Cox, JD
Communications Executive
3D Communications

Rachel Cuccias, MS
Chief Executive Officer
FOIA Professional Services, LLC

Soufiane Dib, PharmD
Associate Director, Global Regulatory
Policy & Intelligence
Gilead Sciences

Tom Dillane, MSc
Manager Regulatory Policy &
Intelligence
Alexion AstraZeneca Rare Disease

**João Duarte, MSc, MPharm, FRAPS,
FTOPRA**
Vice President, Head of Global
Regulatory Affairs Excellence
Ipsen

**Pedro Franco, PhD, PharmD, MBA,
MSc**
Head of Europe Global Regulatory and
Scientific Policy
Merck Serono Limited UK

Patrick Frey
Senior Director, Regulatory Policy
Neurocrine Biosciences

Rudy Fuentes, PhD, RAC-US
Director Regulatory Affairs
PPD clinical research business of
Thermo Fisher Scientific

Purba Ganguly, MSc, CPhT
Senior Consultant
Sunrise Consulting LLC

Hannah Hapner Hogan, MSc
Manager, Regulatory Affairs
Cencora, Global Consulting Services US

Emily Huddle, BSc
Associate Director
Gilead Sciences

John Joines, RPh
Senior Manager Regulatory Affairs
PPD clinical research business of
Thermo Fisher Scientific

Sam Kay, MPharm
VP, Pharma
Basil Systems

Stephanie Sabatino Kelly, JD, MS
Global Head Regulatory Intelligence
and Policy
Kyowa Kirin, Inc.

Anusha Kesireddy, PhD, MS, BPharm
Manager, Regulatory Affairs
Cencora, Global Consulting Services US

Robert F. Kester, MS
Associate Vice President Global
Regulatory Affairs
Merck & Co., Inc.

**Elayne Kimmet, MBA, CQA,
RAC-Global**
Global GxP Policy and Regulatory
Intelligence
Vertex Pharmaceuticals

Jeff MacDonald, PharmD, RPh
Associate Director, Global Regulatory
Policy and Intelligence
BeOne Medicines

Kieran Maher, MSc
Associate Director, Regulatory Policy &
Intelligence
Alexion AstraZeneca Rare Disease

Alex May, MS

US Lead, Regulatory Policy
Genentech

**Aleksandr Merenkov, PharmD, MS,
MBA, RAC-Drugs**

Director, Global Regulatory Intelligence
Genmab US, Inc.

Kirsten Messmer, PhD, RAC-US

Owner
KM Intel LLC

Chelsea Miller, MA

Senior Consultant, Regulatory Affairs
The Bracken Group

Amin Osmani, MSc, MSc

CEO
Cedience Inc.

Brandy Proctor, MS

Regulatory Policy Manager
GSK

Amra Racic, MBA

VP Global Government Strategy
Veeva MedTech

Marco Rafael, PharmD, MBA

Policy Leader - PD Regulatory Science
F. Hoffmann-La Roche

Sean Schofield, PharmD, MS

Principal Regulatory Affairs Specialist
PPD clinical research business of
Thermo Fisher Scientific

**Charity-Anne Metz Schuller,
PharmD, MSCR, RAC-US**

Executive Director, Regulatory Affairs
and Head of Regulatory Intelligence
and Delivery
PPD clinical research business of
Thermo Fisher Scientific

Patterson Shafer

Managing Director
FTI Consulting

Eliza Shearer

Principal Regulatory Lead, Digital
Health Solutions
Convatec

Joshua S. Silverstein, PhD

Director, Regulatory Policy &
Intelligence Americas
Stryker

Lindsay Simon, RAC-Drugs

Senior Manager
3D Communications

Thomas Stover, PhD, MBA

Senior Director, Principal Consultant
Cencora, Global Consulting Services
US

Joseph M. Thomas, PhD

Regulatory Intelligence Lead
Moderna

Chris Whalley

Head of Global Regulatory Intelligence
and Analysis
Pfizer

Andrew C. Wingen, MS, RAC-Global

Director of Regulatory Policy
Bayer

Raya D. Zerger, MT(ASCP)SBB

Senior Staff, Legislative Initiatives,
Regulatory Affairs
Beckman Coulter, Inc.

Michelle Zucatti, MHA

Communications Executive
3D Communications