

Author Acknowledgments

Editors

Linda McBride, RPh, RAC-US
Partner
IAA Consulting LLC

Siegfried Schmitt, PhD
Vice President Technical
Parexel International

Section Editors

Kimberly Belsky, MS, FRAPS
Executive Director, Regulatory Policy and Intelligence, AdPromo, and Regulatory Operations
Mallinckrodt Pharmaceuticals

Devanshi Maharaja, MSc, MTech
Manager, Regulatory Affairs
The Janssen Pharmaceutical Companies of Johnson & Johnson

Daniel G. Mannix, PhD, FRAPS
Senior Vice President, Regulatory Affairs
IO Biotech

Flora Siami, MPH
Senior Vice President
NESTcc

Kip Vought
Partner
IAA Consulting LLC

Authors

Kholoud Mamdouh Abdelfattah, MSc
Clinical Variations Unit Manager
Egyptian Drug Authority

Bayan A. Arar, BPharm, RPh
Healthcare & Life Sciences Consultant

Sharry Arora, MPharm, RAC-Drugs
Regulatory Affairs and Pharmacovigilance Manager
Xeolas Pharmaceuticals Limited

Simon Authier, DVM, PhD, MSc, MBA
Principal Director
Charles River Laboratories

Ajay Babu Pazhayattil, DBA, MPharm
Partner
Itaan Pharma Inc.

Charlene F. Barroga, PhD, DABT
President & CEO
Tessellux LLC

Nicole Beard, PhD, MSc
Founder, Head International Regulatory Affairs
Biogecho Consulting Sarl

Prashant Bhatia, MS
Associate Director, Medical Devices and Combination Products
AstraZeneca Pharmaceuticals

Jennifer G. Brown, PhD, RAC-US
Director, Toxicology
MacroGenics

Timothy A. Candy, PharmD, MS, BCPS
Principal Consultant, Regulatory Affairs
Opus Regulatory, Inc.

Monique J. Carter, MS, RAC-US, FRAPS
Senior Director, Global Regulatory Sciences - Internal Medicine
Pfizer, Inc.

Mantej (Nimi) Chhina, PhD, JD, MSc
Executive Director, Head of Global R&D and Regulatory Policy
BioMarin Pharmaceutical Inc.

Rowena Cook, MS, RAC-Global
Senior Regulatory Affairs Specialist
Twist Bioscience

Shuli Cui, MS, RAC-US
Senior Manager, Regulatory Affairs
Alnylam Pharmaceuticals, Inc.

Cristina Damatarca, MD, PgDip
President and Founder
SafePharm LLC

Pragnesh Donga, MPharm, MBA, RAC-Drugs
Zydus Lifesciences Limited

Robert Falcone, PhD, FRAPS
Senior Regulatory Affairs Manager
Prestige Consumer Healthcare

Stefanie Fasshauer, MBA
Head of Regulatory Affairs, APAC
PharmaLex

Margaret L. Fleming, PhD, MSE
Senior Associate
Exponent

Anu Gaur, PhD, MBA, MSRA, RAC-Global, RAC-US
President
SYNERGY Global Regulatory Affairs Consultancy, Inc.

Amrita Ghosh, RAC-US
Senior CRC and Regulatory Lead
Stanford University, Nuclear Medicine

Ruchi Gupta, MS
Regulatory Program Director

Alan M Hoberman, PhD, DABT, ATS
Executive Director, Global Developmental,
Reproductive and Juvenile Toxicology
Charles River Laboratories

Nidhi Kotecha, PhD, MPharm, RAC-Drugs
Senior Manager, Quality Assurance
Gates Biomanufacturing Facility

Ching Li, PhD
Senior Manager
Biotest Pharma GmbH

Yingying Liu, MS
Associate Director
CSL

Anne Marie Woodland, MS, RAC-EU, RAC-US
Senior Vice President, Regulatory Affairs
Beam Therapeutics

Danini Marin, MSc
Regulatory Affairs Consultant

Amanda M.G. McEwen, MRes
Vice President, Clinical Development
Salubris Biotherapeutics, Inc.

Katelyn J. Mulligan, MS
Senior Submission Manager
Bristol Myers Squibb

Parvarsha Nafees, PharmD
Senior Associate Manager Regulatory
Affairs
Martin Dow Limited

Kingman Ng, PhD
Executive Director, Global Regulatory
Affairs CM&C
Eli Lilly and Company

Hongbo Pan, MBA
GRA Head of China and China R&D site
lead (Shanghai and Beijing)
CSL

Viktória Pásztor, MS
Senior Regulatory Affairs Associate
Parexel Hungary

Komalkumar Patel, MS
Associate Director, Pharmaceutical
Development,
Experic

Grzegorz Podrygajlo, PhD
Director, Global Manufacturing Support,
Global Regulatory Affairs, CMC
CSL

Azzurra Raviza, MS
Senior Director, Global Regulatory Affairs
Pfizer Inc.

Zaida Recinos-Vasquez, MS
Global Regulatory CMC Strategist
Pfizer Inc.

Brian M Roche, PhD, DABT, DSP
Executive Director, Global Safety
Pharmacology
Charles River Laboratories

Darlene (Dar) Rosario, MBA, RAC-US
Principal Consultant RA, QA, Combination
Products, Biotechnology
Velocity Consulting Inc

Barbara A. Rusin, MS
Owner/Independent GxP Consultant
Phoenix Select Regulatory Consulting, LLC

Leonor Pessanha Saldanha, PharmD, MS
Principal Regulatory Affairs Specialist
PPD

Jennifer K. Saxe, PhD
Global Lead, Environmental Safety &
Sustainability
Johnson & Johnson Consumer Health

Kathrin Schalper, PhD, RAC-CAN, RAC-Devices, RAC-EU, RAC-US
Principal Consultant, Regulatory Affairs
Senita Consulting, LLC

Payal Shah, MS, RAC-US

Kurt M. Stahl
Senior Toxicologist
MacroGenics, Inc.

Beat U. Steffen, MSc, MBA, FRAPS
Founder & CEO
confinis

Jesshanie Tabaniag, RPh
International Regulatory Manager
Roche Products Limited - UK

Blaine Van Leuven, MS, RAC-Global
Executive Director, Regulatory and
Strategic Development - CMC
Caidya

Tyler Vandivort, PhD, DABT, RAC-Drugs
Director of Regulatory Affairs and
Operations
Amplicore Pharma

Christinne V. Villanueva, MS
Manager, Regulatory Affairs
Aura Biosciences, Inc

Chauneen Leah Wood, MS, RAC-US
Director, Regulatory Affairs
Verathon, Inc.

Nikolaos Zacharias, MSc
Senior CMC RA project manager

Marjorie E. Zettler, PhD, MPH
Executive Director of Clinical Science
Regor Pharmaceuticals, Inc.

Yuwei Zhang, MD, PhD, MBA, MPH
RWD Analytics Director
Parexel

Table of Contents

Section I: General Information

Chapter 1: Healthcare Landscape and Drug Development.....	1
Ruchi Gupta, MS	
Chapter 2: The Drug Development Continuum, Preclinical to Market Access.....	5
Darlene Rosario, MBA, RAC-US; Pragnesh Donga, MPharm, MBA, RAC-Drugs; Kathrin Schalper, PhD, RAC-US, RAC-EU, RAC-Canada, RAC-Devices	
Chapter 3: International Harmonization via ICH, WHO, and other Global Initiatives.....	19
Anu Gaur, PhD, MBA, MSRA, RAC-US, RAC-Global	

Section II: Nonclinical Studies

Chapter 4: Principles of Good Laboratory Practice and Nonclinical Development.....	29
Kurt Stahl, BS; Jennifer G. Brown, PhD, RAC-US	
Chapter 5: Safety Pharmacology Studies	37
Charlene F. Barroga PhD, DABT; Brian M. Roche, PhD, DSP, DABT; Simon Authier, DVM, PhD, MSc, MBA	
Chapter 6: Pharmacokinetic and Toxicokinetic Studies	53
Tyler Vandivort, PhD, RAC-Drugs, DABT	
Chapter 7: Genotoxicity Studies	63
Tyler Vandivort, PhD, RAC-Drugs, DABT	
Chapter 8: Carcinogenicity Studies	73
Tyler Vandivort, PhD, RAC-Drugs, DABT	
Chapter 9: Developmental and Reproductive Toxicity Assessments	85
Charlene F. Barroga, PhD, DABT; Alan M. Hoberman, PhD, DABT, ATS	
Chapter 10: Regulatory Environmental Risk Assessment of Human Pharmaceuticals.....	99
Margaret L. Fleming, PhD; Jennifer K. Saxe, PhD	

Section III: Chemistry, Manufacturing, and Controls

Chapter 11: The Global Regulatory Process for the Registration of Active Substances	111
Darlene Rosario, MBA, RAC-US; Yuwei Zhang, MD, PhD, MPH, MBA; Robert Falcone, PhD, FRAPS, FTOPRA	
Chapter 12: Coordinating Drug Supply for Clinical and Nonclinical Development	125
Ajay Babu Pazhayattil, DBA, MPharm; Payal Shah, MS, RAC-US	
Chapter 13: Pharmaceutical Development Studies and Manufacturing Experience	141
Komalkumar Patel, MS; Nikolaos Zacharias, MSc; Kingman Ng, PhD; Beat U. Steffen, MSc, MBA, FRAPS; Nicole Beard, PhD, MSc	
Chapter 14: Analytical Development – Testing and Stability	159
Blaine Van Leuven, MS, RAC-Global; Nidhi Kotecha, MPharm, PhD, RAC-Drugs	