

Author Acknowledgments

RAPS and the lead editors, Linda McBride and Pallavi Trivedi, thank the following subject matter experts for sharing their experience and knowledge and volunteering their time to contribute to this first edition of Postapproval Changes for Drugs: A Practical Guide.

Judy Bingham, MHA

Director
Easington Pty Ltd
Australia
Chapters 4 and 8

Juliane Carvalho, MS, RAC-Drugs

Lead Regulatory Health Project Manager
US Food and Drug Administration
US
Chapter 15

Hakima Hoseh, RAC-Drugs

Regulatory Affairs Senior Manager
Hikma Pharmaceuticals
Jordan
Chapter 5

David Jefferys, MD

Senior Vice President
Eisai
US
Preface

Dachelle Johnson, PharmD, RAC-US

AstraZeneca
Global Development Scientist Director
US
Chapter 20

Yingying Liu, MSc

Associate Director
CSL Behring
Switzerland
Chapter 12 and 17

Murphy Mao, MSc

Senior Regulatory Affair Manager
CSL Behring
China
Chapter 17

Linda McBride, RPh, RAC-US

Regulatory and Compliance Consultant
US
Preface, Chapters 9, and 11

Karin McIntosh, MPharm, RAC-Drugs

Vice President, Head of Regulatory Affairs
NexImmune Inc.
US
Chapters 7 and 16

Melodi McNeil, RPh, MS

Director, Regulatory Policy and Intelligence
AbbVie
US
Chapter 1

Moonmoon Mishra, MPharm

Senior Manager, Regulatory Affairs
Viatris Inc. (Erstwhile Mylan Pharmaceuticals Inc.)
India
Chapters 6 and 7

Faustin Ndindayino, PhD

CEO and Managing Director
Afrobridge Pharma Ltd.

Mali

Chapters 19 and 22

Hongbo Pan, MBA

Head of China RA and R&D Site (Shanghai
and Beijing)

CSL Behring

Chapter 17

Hadeer Abdulbasir Sayed

EMEA Regulatory Affairs Lifecycle Manager
Egypt

Chapters 13 and 14

**Kathrin Schalper, PhD, RAC-US, RAC-EU,
RAC-CAN, RAC-Devices**

Principal Consultant, Regulatory Affairs and
Managing Member

Senita Consulting, LLC

US

Chapter 10

Seema Singh, MSc

Group Leader Regulatory Affairs and CMC
Mitsubishi Tanabe Pharma Corp.

Japan

Chapter 9

Shakti Tripathy, MPharm

Regulatory Affairs

Dr. Reddy's Laboratories Ltd.

India

Chapter 2

Pallavi Trivedi, MPH, RAC-US

Senior Manager

Viartis

Chapters 3 and 21

Blaine Van Leuven, MS, RAC

Director, Regulatory CMC

Premier Consulting

US

Chapter 6

Julie Watchorn, MSc, RAC-EU

Senior Regulatory Affairs Consultant

Parexel

Ireland

Chapters 11 and 21

**Fatima Zaid Abu Zanat, MSc, RPh, RAC-
Drugs, RAC-Devices**

Regional Director of Regulatory Affairs and
Scientific Office

Middle East, Turkey, and Africa

Ispen

UAE

Chapter 18

Jing Zhou, MS

Manager, Regulatory CMC

PTC Therapeutics

US

Chapter 15