

Preface

Welcome to the inaugural edition of *Postapproval Changes for Drugs: A Practical Guide*, developed for regulatory professionals of all levels, including newcomers and seasoned professionals as well as academics and governmental employees. This new book was created to raise the awareness of the regulations, tools, and pathways for medicinal products for changes after the initial approval and is a valuable resource for all who participate in the commercialization of drugs and biological products, globally. The content should be considered as dynamic as the resources from which it is based, and the reader is advised to consult the resources for each chapter for up-to-date information.

The book is organized into five distinct sections according to the type of change being implemented. Each section is comprised of chapters covering various countries, including the Americas, Europe, Asia Pacific, Middle East North Africa, and Africa. The book includes a global perspective of postapproval changes for drugs and biological products presenting the regulatory requirements, application of the requirements, and case studies that illustrate real-life scenarios.

Section I opens the publication with the review of applicable regulatory requirements for marketing authorization transfers, renewals, and administrative changes. **Chapter 1** describes the legislation applicable to the United States, followed by **Chapter 2** covering Argentina, Brazil, Canada, Chile, and Mexico. **Chapter 3** presents the specifics for Europe, including the European Union, United Kingdom, and Switzerland. **Chapter 4** encompasses the requirements for Asia Pacific countries and **Chapter 5** provides the requirements for Middle East North Africa.

Section II focuses on changes that impact chemistry, manufacturing, and controls also known as quality changes. **Chapter 6** includes the regulations and requirements for Argentina, Brazil, Canada, Chile, Mexico, and the US. **Chapter 7** describes the requirements for Europe, followed by expectations for Australia, New Zealand, Malaysia, and Singapore in **Chapter 8**, and finally **Chapter 9** explains the requirements for Japan to complete Section II.

In **Section III**, the legislation as well as the impact of changes for safety and product information related changes is discussed, starting with **Chapter 10** covering the Americas, specifically Argentina, Brazil, Canada, Chile, Mexico, and the US. **Chapter 11** explains the legislation for Europe and **Chapter 12** defines the expectations for China. **Chapter 13** provides an overview of the requirements for MENA followed by **Chapter 14** which provides the regulatory considerations for Africa.

Section IV reviews the postauthorization commitments and studies as marketing authorization approval requirements. **Chapter 15** presents the regulator expectations for Argentina, Brazil, Canada, Chile, Mexico, and the US. **Chapter 16** describes the details of the pathways in Europe, specifically for the EU, UK, and Switzerland. **Chapter 17** explains the considerations for China. **Chapter 18** provides details for MENA and **Chapter 19** covers the requirements in Africa.

Section V provides the expectations for postmarketing surveillance and risk management. **Chapter 20** includes the requirements for Argentina, Brazil, Canada, Chile, Mexico, and the US. **Chapter 21** provides guidance for the EU, UK, and Switzerland. **Chapter 22** wraps up the book with the roadmap for Africa.

Understanding postapproval regulatory requirements can be challenging; however, it is important for maintaining compliance and ensuring medicinal product approval. I hope that you find this book to be a valuable resource to facilitate strategic discussions and to collaborate on the necessary updates and changes that occur after initial marketing application approval in order to support the continued availability of new therapies to diagnose, prevent, treat, and cure diseases worldwide.

Editor

Linda McBride, RPh, RAC-US

Regulatory and Compliance Consultant