

Preface

The evolving complexity of human therapeutics requires the development of novel drug delivery systems. This book encapsulates in a single volume the concepts essential for understanding the science and technology associated with the research and development of long acting injections and implants. It provides a comprehensive overview of the scientific and regulatory challenges associated with these delivery systems.

Critical contributions to this area are the array of formulations that make up the spectrum of long acting injections and implant dosage forms. These include microspheres, liposomes, in situ forming depots, suspensions, implants, lipophilic solutions, and osmotic implants. Such formulations have the potential to maintain therapeutic drug concentrations for durations from days to months, can be engineered to maintain characteristics such as zero-order or pulsatile drug release, and, in some cases (e.g., liposomes) can provide targeted drug delivery to the site of action. These attributes lead to increased patient compliance and convenience, reduced fluctuations in plasma profiles, and reduced plasma concentrations making it possible to administer higher drug concentrations to the site of action while reducing the overall dose. Thus, unwanted side effects can be minimized or reduced. In addition, long acting injections and implants can provide a means for the delivery of drugs that are subject to degradation in the harsh environment of the gastrointestinal tract, that undergo extensive first pass metabolism, or that exhibit poor bioavailability when such molecules are orally administered.

Long Acting Injections and Implants begins with chapters that provide basic concepts explained in a simple, clear, and concise manner. In subsequent chapters additional material, expansions on the basic scientific concepts underpinning research and development of such dosage forms, and examples of technological developments in this area are comprehensively reviewed and discussed. The introductory chapter provides a brief description of the types of systems and major areas of current application and research. The *Historical Overview* chapter provides a chronological overview of the historical developments associated with long acting injections and implants providing sufficient background to enable the reader to appreciate the historical development of the area and to use that knowledge as a foundation for the

development of the next generation of products. The *Host Response* chapter introduces the reader to the body's response to biomaterials/foreign bodies and the influence of environmental conditions on the design and development of long acting injections and implants. The *Anatomy and Physiology* chapter describes the biological features of the site of administration that are relevant to the development of long acting injections and implants. The following two chapters provide comprehensive information on drug candidates, clinical objectives, and disease states. The next series of chapters of the book focus on aspects related to the research and development of specific injection and implant dosage form types. In addition to the systems mentioned above, chapters are also provided on micro- and nanoemulsions, PEGylation of nanocarriers, self-assembling lipid formulations, microfabricated technologies, drug eluting stents, delivery of peptides and proteins, and delivery of vaccines. These overviews are followed by chapters that describe and discuss special considerations unique to the injection route including sterilization and in vitro release testing (and in vivo/in vitro correlation). In the final chapter of the book, an overview of the regulatory considerations associated with the registration of long acting injections and implants is provided.

Long Acting Injections and Implants has been written with the objective of both enlightening someone just starting in the field (e.g., a new scientist or experienced scientist switching fields) and while at the same time providing the in-depth knowledge that is beneficial for a skilled worker in the field. It is hoped that the reader will find this volume useful and intriguing for both the variety of scientific system types that provide long acting therapy and for the wide range of scientific and technical topics that are involved in the research, development, and registration of long acting injections and implants that provide state of the art therapy to patients.

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<http://www.springer.com/978-1-4614-0553-5>

Long Acting Injections and Implants

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2012, XVI, 560 p., Hardcover

ISBN: 978-1-4614-0553-5