

Preface

Long-acting veterinary formulations play a significant role in animal health, production, and reproduction within the animal health industry. Such technologies offer beneficial advantages to the veterinarian, farmer, and pet owner. These advantages have resulted in long-acting formulations growing in popularity in recent years.

The pharmaceutical scientist is faced with many challenges when innovating new products in this demanding field of controlled release. This volume provides the reader with a comprehensive guide on the theories, applications, and challenges associated with the design and development of long-acting veterinary formulations. The authoritative chapters of the book are written by some of the leading experts in the field. It covers a wide scope of areas including the market influences, preformulation, biopharmaceutics, in vitro drug release testing, and specification setting to name a few. It also provides a detailed overview of the major technological advances made in this area. As a result, *Long Acting Animal Health Drug Products* covers everything a formulation scientist in industry or academia or a student needs to know about this unique drug delivery field to advance health, production and reproduction treatment options, and benefits for animals worldwide.

In chapter 1 Sabnis and Rathbone define the current animal health markets for farmed animals and evaluate the opportunities that exist. The chapter provides an outlook for future projections of growth in the livestock industry and the likely resultant demands of the farmed animal health market. In the second chapter Linda Hoorspool conducts a similar analysis (with quite different conclusions) for the companion animal market.

The anatomy and physiology of the farmed and companion animals are provided by Ellis and Sutton, respectively. These chapters describe the large differences between ruminant (cattle and sheep) and monogastric animals (specifically cats and dogs) and highlight the different challenges (and opportunities) faced by formulation scientists in designing and developing long-acting veterinary products for these two physiologically and anatomically different types of animals.

Chapter 5 provides a comprehensive overview of the physicochemical principles of controlled release veterinary pharmaceuticals. In this contribution Fletcher et al. describe the basic physical and chemical properties relevant to drug formulation

which includes the active pharmaceutical ingredient, excipients, and final product. The chapter also highlights the importance of physical and chemical attributes of compounds in the selection of ingredients; development of dosage forms; and their significance with respect to active and final product assessment, characterization, performance, and quality. Sutton describes the basics of biopharmaceutics and its relevance in veterinary drug delivery. This chapter discusses studies that emphasize the similarities and differences in species and routes of administration. From nasal and ocular to transdermal and oral, examples of formulations for veterinary practice are discussed. The main concepts related to analytical testing of veterinary drug products and the development of specifications for critical quality attributes are addressed by Brumfield. This excellent and comprehensive chapter will be of value to anyone working in the industrial setting. Brumfield describes pragmatic strategies for the development and use of analytical specifications throughout the veterinary product development and commercialization life cycle. Also presented are typical analytical testing requirements for quality assessment and registration of selected types of products in major markets (USA, EU, and Japan), and unique challenges related to several veterinary-centric dosage forms including medicated articles for preparation of feeds and drinking waters, and topical parasiticide preparations. The challenges of developing and undertaking *in vitro* drug release testing of veterinary pharmaceuticals are described in the following chapter by Higgins-Gruber. Long-acting veterinary dosage forms tend to be more complex and varied because of the diversity of species and size of the animals. Therefore, the development of *in vitro* drug release tests for such products can be challenging and unconventional with respect to the expectations from the regulatory agencies. Higgins-Gruber describes the principles taken into consideration when developing an *in vitro* drug release test for long-acting veterinary pharmaceuticals that is easy to perform in a quality control environment whilst being discriminating with respect to the impact of critical quality attributes on *in vivo* behavior.

The remaining contributions of the book describe technological advances in the field of long-acting veterinary products. Chapters devoted to long-acting rumen drug delivery systems (Vandamme), intravaginal veterinary drug delivery (Rathbone), long-acting injections and implants (Cady), intramammary delivery technologies (Alany), veterinary vaccines (Elhay), and delivery systems for wildlife (McDowell) all provide a wealth of information and insight into the current strategies and contemporary research adopted in the development of long-acting veterinary drug delivery systems.

In the final chapter of the book Baird examines the emerging drug discovery technologies in both the human and animal drug delivery fields and discusses the potential for cross over of the learnings, technologies, and outcomes from these areas that result in “spin off” benefits for veterinary medicine. The chapter makes for some interesting reading.

We thank all the authors for their time and effort to put pen to paper to share their experiences and knowledge in this volume. Without their interest and commitment to the area of long-acting animal health products this book would not be the treasury of knowledge that it is.

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Long Acting Animal Health Drug Products

Fundamentals and Applications

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