

Preface

Recent years have seen the rise of biopharmaceuticals as promising tools in the treatment, prophylaxis and diagnosis of multiple diseases. With more than 300 molecules approved worldwide (while others are on late stages of development) and an estimated global market of over US\$ 166 billion by 2017 [1], biopharmaceutical medicines are now an important part of the armamentarium of modern therapeutics [2–3]. The term “biopharmaceuticals” (often used interchangeably with “biologics” or “biological products”) is widely used, but its definition has been often neglected and a topic of discussion [4]. For the purpose of this book, biopharmaceuticals are broadly defined as molecules with inherently biological origin and/or manufactured using biotechnological techniques that usually comprise the use of living organisms, cells or their components. This class of pharmaceuticals is fairly heterogeneous and includes different molecular entities such as protein- and peptide-based molecules (antibodies, hormones, toxins, enzymes, growth factors, among others), and genetic material (plasmid DNA, small interference RNA, ribozymes, aptamers, among others).

Even if parenteral routes are typically considered for their administration, the mucosal delivery of biopharmaceuticals may present important advantages that make it preferential, namely by providing direct access to target sites, abbreviating patient compliance issues, mimicking physiological processes, enhancing safety, and allowing taking advantage of the distinctive characteristics of the mucosal immune system. However, frequent unfavorable physical-chemical properties of these active biomolecules lead to reduced stability in different biological fluids and poor permeability. This poses an important hurdle to their mucosal administration and the attainment of significant bioavailability values. In particular, challenges in developing adequate materials and delivery systems that allow the use of biopharmaceuticals in daily life are huge [5].

Accumulated knowledge and achievements in developing successful biopharmaceutical delivery systems that may explore the mucosal pathway to exert local effects or enter the bloodstream are emerging. This book aims at providing a concise and up-to-date overview of the biological features justifying the use of different human mucosa as delivery routes for biopharmaceuticals, the technological strategies that have been adopted so far regarding the optimization of mucosal potentialities, as well as the challenges that arise with the advent of new biopharmaceutical drugs

and alternative means of administration. These exciting and innovative topics are addressed in their different perspectives by some of the most important academic authorities and industrial experts in the field. The work is divided into four parts. The first section of this book addresses general aspects of the biology of mucosal tissues and their unique aspects towards beneficial or deleterious interaction with biopharmaceuticals and their delivery systems. The second section is dedicated to the different delivery strategies that have recently been investigated for different mucosal sites. The third section describes the development and clinical applications, either factual or potential, of particular pharmaceutical delivery systems/products enclosing biopharmaceuticals for mucosal delivery. Special focus is set on the most successful case studies of recent years, namely by some of those directly engaged in developing such solutions in a concise and practical way. The last section briefly centers on pertinent aspects about the regulatory, toxicological and market issues of biopharmaceuticals intended for mucosal administration.

We hope that scientists and researchers in the fields of drug delivery, materials and biomedical sciences and bioengineering, as well as professionals in the pharmaceutical, biotechnology and health-care industries will find in this work an important compendium of fundamental concepts and practical tools for their daily research and activities. In particular, extensive emphasis on case studies of successfully developed and some already marketed systems/products for mucosal delivery of biopharmaceuticals was pursued. Also, focus on regulatory issues makes this book a valuable tool for decision-makers in the pharmaceutical industry and in regulatory bodies worldwide.

January 2014

José das Neves
Bruno Sarmiento

References

1. International Market Analysis Research and Consulting Group. Global Biopharmaceutical Market Report & Forecast (2012–2017). 2012.
2. Walsh G. Biopharmaceutical benchmarks 2010. *Nat Biotechnol.* 2010;28(9):917–24.
3. Walsh G. New biopharmaceuticals—a review of new biologic drug approvals over the years, featuring highlights from 2010 and 2011. *BioPharm Int.* 2012;25(6):34–38.
4. Rader RA. (Re)defining biopharmaceutical. *Nat Biotechnol.* 2008;26(7):743–51.
5. Jorgensen L, Nielson HM, editors. Delivery technologies for biopharmaceuticals: peptides, proteins, nucleic acids and vaccines. Chichester: Wiley; 2009.

Mucosal Delivery of Biopharmaceuticals

Biology, Challenges and Strategies

das Neves, J.; Sarmento, B. (Eds.)

2014, XIX, 601 p. 134 illus., 23 illus. in color., Hardcover

ISBN: 978-1-4614-9523-9