METHODS IN MOLECULAR BIOLOGY™

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Therapeutic Proteins

Methods and Protocols

Second Edition

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Preface

The first proteins developed as therapeutic agents were purified naturally occurring proteins or recombinant versions thereof. In recent years, the field of therapeutic proteins has expanded, and more effort has been put into increasingly sophisticated protein design and engineering efforts. However, design, discovery, and engineering of a new protein are only the first steps towards the development of a therapeutic molecule. Once a potential protein drug has been identified, the next critical step is the production of sufficient authentic material for testing, characterization, and clinical trials. If a candidate protein drug makes it through this lengthy and costly process, methodology that allows the production of the protein on a scale large enough to meet demand must be implemented. It is also necessary to have robust methods for the purification, characterization, viral inactivation, and continued testing of the final protein product.

The aim of this second edition of *Therapeutic Proteins: Methods and Protocols* is to cover each of these key aspects of protein drug production. As in the first edition, attention is given to production, purification, and characterization of protein therapeutics. This second edition emphasizes new developments since the publication of the first edition in 2005. This second edition also includes additional emphasis on discovery, including new display and screening methods as well as the design and engineering of new types of therapeutic proteins. There is also discussion of computational and bioinformatics methods, and chapters on safety aspects of therapeutic protein development. All contributing authors are based at highly esteemed industrial and academic institutions from around the world.

This book contains complete protocols set out in a simple step-by-step manner. It opens with an introductory chapter that reviews the history of the field and contains thoughts on the direction of future developments. A number of other chapters provide an overview of a key area of therapeutic protein development. Most chapters are experimental protocols that contain a useful introduction describing the theory and background to a particular method, which is then followed by a list of all equipment and materials required to complete the protocol. The Methods section describes every step of the protocol and is cross-referenced to a Notes section that describes possible difficulties or problems that may arise, alternative methods, and invaluable hints.

A large number of people have helped organize this book so that it ultimately provides a very useful resource to all those working in the field of therapeutic proteins. We would especially like to thank all contributors for their excellent chapters based on expert knowledge and experience. We are also grateful to John Walker, the series editor, for asking us to edit this book, and for his help and advice in preparing the final product. Thanks also to David Casey and his colleagues at Springer, Humana Press, who have helped put this together.

Gaithersburg, MD, USA
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