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Characterization of Nanoparticles Intended for Drug Delivery

Second Edition

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Preface

It has been 6 years since the first edition of this book introduced methods for the characterization of nanoparticles intended for drug delivery. Since that time, basic and translational research considerably advanced the field of nanotechnology, leading to the clinical development of nanomedicines with greater sophistication and characterization requirements. In response to the growing needs of the nanotechnology community, this second edition book provides up-to-date protocols to characterize nanomaterials intended as drug delivery agents. These new and updated protocols are designed as tools for researchers and pharmaceutical and biotechnology developers to evaluate the clinical potential of nanomedicines in preclinical development. Specifically, they can be used to assess the nanomedicine's physicochemical parameters, toxicity, and safety concerns.

Progress in nanotechnology and biology continues to expand nanomedicine development, while simultaneously introduces new characterization challenges. Chapter 1 discusses the advances in nanomedicine and the obstacles in its evaluation. The remainder of the book contains new or updated protocols for nanomaterial characterization, including methods to test sterility and endotoxin (Chapters 2 and 3), physicochemical features (Chapters 4–8), immunological effects (Chapters 9–18), drug release (Chapter 19), and in vivo efficacy (Chapter 20). While protocols that characterize the physicochemical properties can be applied to nanomedicines intended for all routes of administration, most of the other in vitro protocols in this book are meant to evaluate nanoparticles that are administered intravenously. Most reported nano-based drug delivery agents are designed for intravenous route of administration. Although the methods in this book can be applied to a variety of nanoplatforms, certain assays may need to be individually tailored to the specific technology. Many of these methods have been devised, updated, and validated by scientists at the National Cancer Institute's Nanotechnology Characterization Laboratory (NCL) (https://ncl.cancer.gov) in order to accelerate the development of promising nano-based therapies and diagnostics. NCL continually optimizes and designs new characterization methods to meet the evolving requirements of nanomedicine developers.

There is a significant amount of effort and time put in by NCL and other groups at the Frederick National Laboratory to produce the protocols included in this volume. I would like to thank all the authors who have contributed to this work and made this second edition possible. Distinct recognition goes to the key scientists who developed the methods included in this book and those that serve as scientific leaders at NCL: Drs. Stephan Stern, Marina Dobrovolskaia, Jeff Clogston, and Pavan Adiseshaiah. Supporting their expertise is the dedicated, hands-on work by Edward Cedrone, Alpana Dongargaonkar, Matthew Hansen, Dr. Anna Ilinskaya, Chris McLeland, Barry Neun, Tim Potter, Jamie Rodriguez, Dr. Bhawna Sharma, and Sarah Skoczen. Collaborators, namely Dr. Krishna

Kota and Mackensie Smith, are appreciated for their time to enhance these chapters. Special thanks go out to Dr. Ulrich Baxa and Kunio Nagashima of the Electron Microscopy Lab at the Frederick National Laboratory and their former colleagues, Sarah Anderson and David Parmiter, for their development of advanced microscopy techniques for nanoparticle characterization. Also, I express gratitude to Drs. Maggie Swierczewska Scully and Rachael Crist for their contribution to Chapter 1 and hard work in assembling this book.

Frederick, MD, USA *Scott E. McNeil*

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