Preface

The intent of this book is to provide a basic set of methods for the characterization of nanomaterials for medical use. This is offered to scientists as a survey of methods important in the preclinical characterization of nanomedicines. The chapters will provide methods to characterize the physicochemical properties (e.g., size, aggregation, and surface chemistry), and in vitro immunological and biological characteristics of nanomaterials.

Chapter 1 of this volume presents some of the exciting opportunities that are now being realized in the application of nanotechnology to medicine. Nanotechnology is revolutionizing traditional pharmaceutical design by giving drug developers the toolsets and flexibility of engineering. On the nanoscale, medical researchers can “build” new drugs and diagnostics in ways that seem more akin to constructing a machine than to traditional synthetic chemistry. And in certain ways, nanotech pharmaceuticals behave more like tiny, complex, multipart systems than like traditional small molecule drugs.

Characterizing these complex, multipart systems to ensure they are pure, reproducible, safe, and effective can be challenging. Chapters 2 and 3 outline some of these challenges, including interference – nanoparticles often interfere with standardized methods with long histories of use in the pharmaceutical industry. The remainder of this volume contains protocols for nanomaterial characterization, many of which have been developed at the National Cancer Institute’s Nanotechnology Characterization Laboratory (NCL) – an interagency collaboration among NCI, FDA and the National Institute of Standards and Technology (NIST). NCL scientists developed these protocols to rigorously characterize nanoparticle physicochemical properties, as well as in vitro immunological and cytotoxic characteristics. These methods have undergone extensive in-house validation and are subjected to regular revision to ensure applicability to a variety of nanomaterial types.

As the reader will appreciate, multiple man-years of effort are incorporated into these chapters. Accordingly, I would like to thank all the authors who have contributed to this work and recognize the efforts that made this publication possible. Specifically, I would like to thank the staff at NCL for their heroic dedication over the years to nanoparticle characterization: Drs. Anil Patri, Stephan Stern, and Marina Dobrovolskaia are the key scientists who developed the majority of these methods. Hands-on support to develop and qualify the protocols was also provided on a daily basis by Chris McLeland, Tim Potter, Barry Neun, Sarah Skoczen, Jamie Rodriguez, and Drs. Jeffrey Clogston and Jiwen Zheng. Within the parent organization of the NCL, SAIC-Frederick, thanks go to Kunio Nagashima, David Parmiter, King Chan, and Drs. Haleem Issaq and Jack Simpson. Other important contributors include Drs. Nakissa Sadrieh and Katherine Tyner at FDA for their very informative overview of how nanotech products are regulated and reviewed. At NIST this list of valuable contributors includes Drs. Vince Hackley, Robert Cook and Jaroslaw Grobelny. Finally, let me also thank Dr. Jennifer Hall at NCL for her extensive help coordinating, assembling, and editing this work.

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