

Foreword

The foreword to the first edition of this book started out by noting the increasingly broad scope of products being designated as medical devices. As technologies advance, this continues to remain true and expands further to provide new diagnosis or treatment modalities toward the needs of patients. With this advancement, one must anticipate corresponding concomitant changes to the regulations and requirements governing these products. The technological evolution requires new regulatory approaches to ensure continued confidence in the safety and efficacy of medical devices. Regulations are not static, they evolve constantly, regardless of which country serves as the source of the products. Over the period since the last edition, major regulatory changes pertaining to medical devices have been witnessed in places like the European Union and the US, among others.

As the author described in Chapter 1, healthcare is undergoing a radical transformation driven by uncontrollable cost increases, higher healthcare needs and increased regulatory scrutiny, as well as a shift in payment systems and new payment models. To survive under this environment, healthcare providers are focusing more than ever on controlling the cost of care, being more efficient and delivering improved patient care. As this shift expands, a stakeholder's willingness to pay for a medical device will be tied to its impact on patient outcomes and performance metrics, and medical device manufacturers need to implement a collaborative and comprehensive approach in their product development process (PDP) with customer adoption as the goal; involvement by regulatory professionals early in the process is critical.

While the core educational curriculum for regulatory professionals remains generally the same, this edition captures the aforementioned evolutions and provides a resource of uniform value to both the experienced regulatory professional and those entering the profession and designing their own pathway to success in this vastly enriching field. It can be used as a contemporary and integral bookshelf reference in regulatory affairs departments of all sizes, as well as a routine textbook in expanding academic curricula in regulatory affairs and quality systems.

Our thanks to the many authors who volunteered their time and knowledge in contributing to this book, and especially to the late Pamela Jones, RAPS senior editor, a dear friend who guided the inception of both editions, and whose editorial vision and dedication was inspiring to us all.

Editors-in-Chief

Peter A. Takes, PhD, RAC, FRAPS
Principal
Regulatory Intelligence Associates, LLC

Susumu Nozawa, RAC, FRAPS
Head of Regulatory Policy – North America
Siemens Healthineers

Author Acknowledgments

The Regulatory Affairs Professionals Society would like to express appreciation to the following subject matter experts who shared their experience and knowledge and volunteered their time by contributing to this book. RAPS also would like to recognize the work of the first edition authors who laid the groundwork for this second edition.

Andrea Armando, RAC

Senior Manager, Regulatory Affairs Operations
DiaSorin
Italy

Gert Bos, MSc, PhD, FRAPS

Executive Director and Partner
Qserve Consultancy BV
Netherlands

Stanley F. Chalvire

Member
Morse, Barnes-Brown & Pendleton, PC
US

Xianjun (Catherine) Chen, MS, RAC

Principal Regulatory Specialist
Sports Medicine and ENT
Smith & Nephew
US

Koen Cobbaert, MSEE, MSRM

Chair Software Focus Group
COCIR
Belgium

Sean D. Detweiler

Member/Partner
Morse, Barnes-Brown & Pendleton, PC
US

Scott D. Dickerhoff

Director of Regulatory Affairs-Acoustic
Implants
Cochlear Ltd.
US

David A. Fazzolare

Patent Attorney
Novozymes
US

Anu Gaur, PhD, MBA, MSRA, RAC

Faculty, Regulatory Affairs Graduate Program
College of Professional Studies (CPS)
Northeastern University
US

Jeffrey N. Gibbs

Director
Hyman, Phelps & McNamara, PC
US

Dorota Grabowska, PhD

Senior Scientist
Department of Radiology
Washington University School of Medicine, St.
Louis
US