Introduction

The first question we asked ourselves when the idea came up for this book was: Does the regulatory community really need it? The answer was an unequivocal "yes," and here is why. We are both of an age at which chats with friends and family revolve around ailments and medication more often than we would like to admit. And, as healthcare industry professionals, we are often asked probing questions such as whether a vaccine really has as many side effects as the label says; why a drug costs so much; or why it has taken so long to develop an Alzheimer's drug.

Of course, this book is not written for our friends and family members, but really for the regulatory professionals who need to have the answers to such questions.

So where do we find the answers? Sadly, the information is all over the place – there is an article here, a book chapter there. Some are in Chinese; some are in English; and others in yet another language. There was no single, comprehensive source for a global regulatory perspective on drugs and biologics.

And that is why this book is an absolute necessity for regulatory professionals globally. Does it give you the answers to all and everything? That would be wishful thinking. It does, however, give you, dear reader, the single best source of authoritative regulatory information and guidance that our collaborative of more than 50 global expert authors and we, as editors, can bring you.

We sincerely hope you will enjoy reading it and glean helpful bits of information that answer your questions – and maybe even those of your families and friends. And if you have a minute, do let us know your feedback.

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Linda McBride, RPh, RAC-Drugs, is a partner at IAA Consulting with extensive experience in the science of drug development in the biopharmaceutical industry. Over her career of more than 30 years, she has had direct experience in developing and implementing registration strategies for pharmaceuticals and biologics in various therapeutic areas, from candidate selection through marketing application and postapproval. McBride has significant expertise in preparing teams for successful interactions with health authorities and for delivering approvals for marketing applications for pharmaceutical and biological products while striving to achieve the corporate vision for success. She is a RAPS member and serves on its Editorial Advisory Committee and the Convergence Planning Committee.

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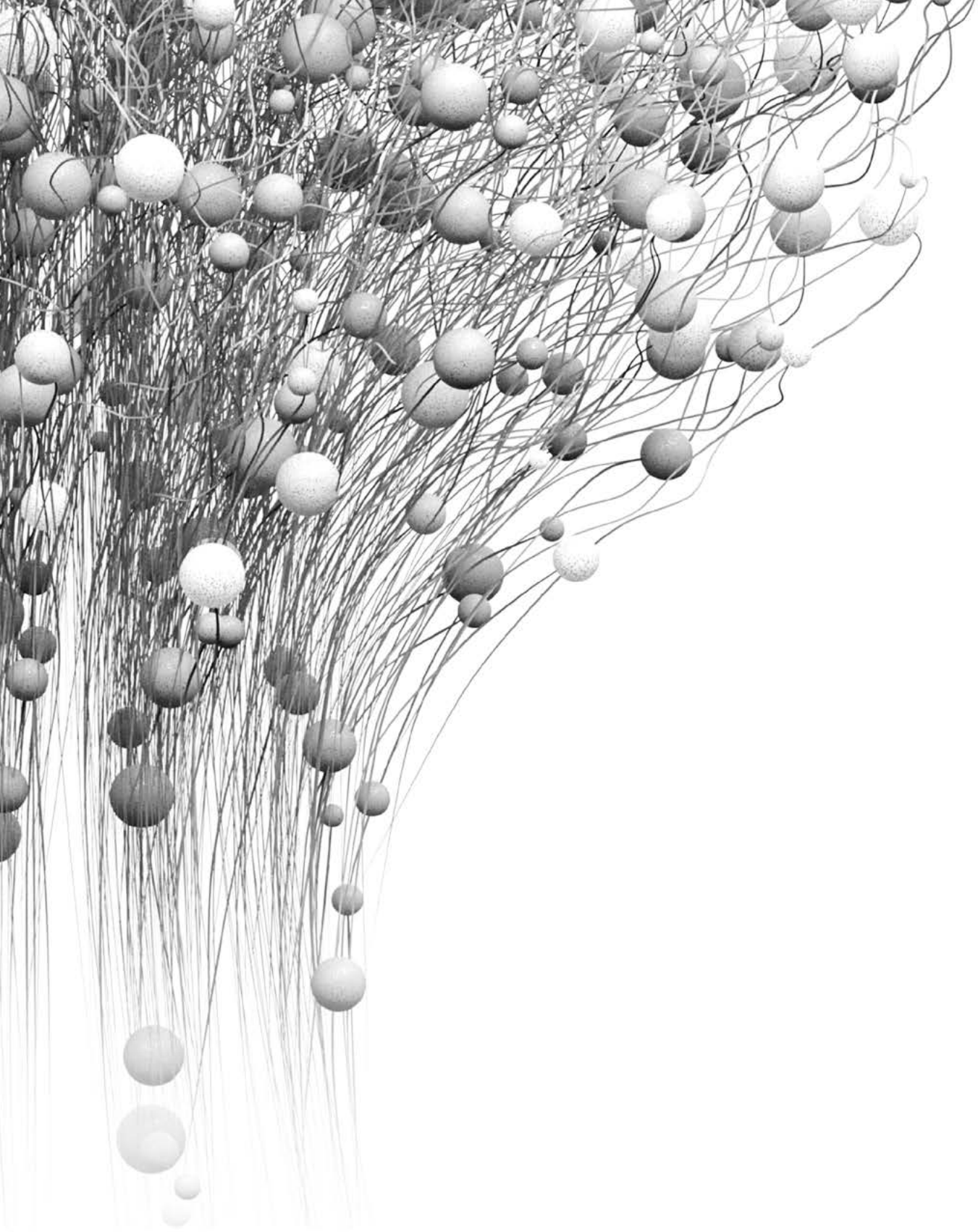
Siegfried Schmitt, PhD, has been Vice President Technical in the Strategic Compliance Consulting group of Parexel International since 2007. He has more than 30 years of experience and expertise in the global pharmaceutical and medical device industries. He provides consulting services to customers in the healthcare industry on all aspects of regulatory compliance, particularly in the design and implementation of effective and efficient quality management systems. The services cover the entire product lifecycle, from the clinical to the commercial phase. Schmitt serves on several editorial advisory committees, has written or contributed to 28 books, and has published well over a hundred articles for renowned journals, including RAPS Regulatory Focus. He has been a member of RAPS since 2010, serves on its Editorial Advisory Committee, and as co-chair of Euro Convergence 2023.



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