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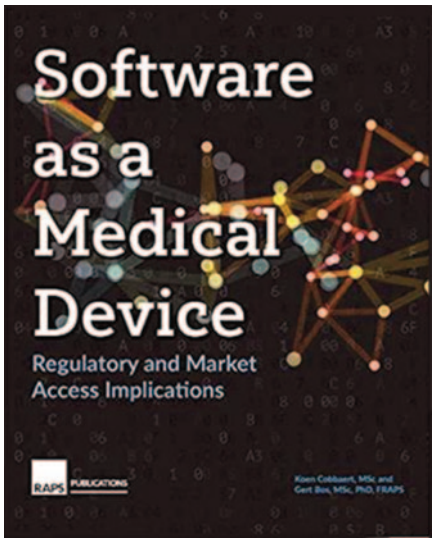

Software as a Medical Device

Regulatory and Market Access Implications

By Koen Cobbaert, Gert Bos, Gloria Hall (editor)
Regulatory Affairs Professionals Society (RAPS) Publications
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As the authors of this book, Koen Cobbaert and Gert Bos, state "software joins the dots, by connecting patients with healthcare professionals and breaking down the boundaries between everyday objects, medical devices, and medicine."

As a medical writer drafting clinical evaluation reports for medical devices and related regulatory documentation, it is extremely important to be fully aware of the implications of medical device software evaluations. In today's medical devices, software is becoming more and more present, and very often, software is integrated into hardware devices to enable them to achieve their medical purpose. In late 2019, I attended a thorough training course called Software as a Medical Device which helped me understand how complex the field of health software is becoming.

Very helpfully, in Spring 2021, the Regulatory Affairs Professionals Society (RAPS) published *Software as a Medical Device, Regulatory and Market Access Implications*, a comprehensive manual covering this complex regulatory landscape. Subject matter experts in the field have collaborated and contributed different chapters to the book.

The book can either be read in hard copy or as an eBook. The eBook version is particularly useful considering the length (240 pages) and the fact that this version allows the reader to run "searches" on the text. After a preface, the book is divided into 15 chapters, each one addressing a different and specific topic on software, from classification to clinical evaluation, risk management, and usability engineering, among others.

Chapter 1 navigates the reader through an introduction to the field, and Chapter 2 defines what "Software as a Medical Device" is. If you do not know the difference between medical device software (MDSW), software as a medical device (SaMD), software in a medical device (SiMD), software modules, wearables, and software as an accessory, both from a conceptual and from a regulatory point of view, this chapter will really help you navigate through those differences. There are significant variations in how different regulatory jurisdictions consider software in the scope of their medical device legislation, and this is something medical writers should be aware of. Chapter 2 will definitely help readers understand these contrasts.

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Chapter 3 defines what constitutes "Software as an In-Vitro Diagnostic Device", describing qualifying in-vitro diagnostic software in the EU, the US, and Canada. Again, various jurisdictions may apply slightly different definitions. These three chapters are the foundation upon which a medical writer may build further knowledge. The text helps the reader fully understand the regulatory definitions and draws attention to the differences and peculiarities.

After a manufacturer establishes that a product is within the scope of the EU Medical Devices Regulation (MDR), it needs to be classified. Classification rules rely on various regulatory concepts that a manufacturer needs to learn before classifying their products. Chapter 4 covers "Classification of Medical Device Software" and provides a broad insight into this topic.

Chapter 5 on "Clinical Evaluation of Software" addresses one of the areas in which regulatory medical writers are most often involved: drafting the Clinical Evaluation Report and related documentation. On one hand, there is the drive to foster innovation, and on the other, a need to protect patient safety. Clinical evaluation ensures that the standards on safety and performance are guaranteed. However, the rapid development of software as medical device applications brings both opportunities and challenges. The book has a series of chapters addressing the risks of medical device software. The "Safety and Risk Management of Software" is covered in Chapter 6, and "Security Risk Management" in Chapter 7.

Some rather technical chapters follow that address the development phase of devices: "Software Development" (Chapter 8), "Open Source and Third-Party Software Components" (Chapter 9), "Software Usability Engineering" (Chapter 10), and finally, "Artificial Intelligence"

(Chapter 11). These chapters are highly technical and may not be suited to all medical writers.

The quality and reliability of health apps is fundamental to having physicians prescribe them. The quality and reliability of a health app may be judged on nuances such as the app's privacy settings, use of patient data, and ethics. Physicians need to have the certainty that a given app fulfils a set of quality and reliability parameters to feel at ease prescribing it. Each of these aspects is addressed in Chapter 12, "Quality and Reliability of Health Apps".

It is no wonder that the digital distribution of health apps is rather complex. Regulatory guidance has addressed physical product distribution, and the digital path proves to be challenging. There are many economic operators involved, and contractual nuances do not make the task easy. Guidance on regulatory implications of digital distribution models is reviewed in Chapter 13.

Manufacturers, and more experienced medical writer colleagues, frequently use medical device acronyms without necessarily defining them. Medical writers who are new to the field may find the list of acronyms used in the book and presented at the end very helpful as they build up their knowledge in this area of medical writing.

Personally, I found the figures and tables in the book very useful. The authors use these to summarise complex or lengthy concepts. The index at the beginning of the book is well designed and will help the reader find what they need at a glance.

This book presents an updated overview of the topic. Still, it should also be considered that medical device software is a continuously evolving topic. New guidance documents may be released at any moment, particularly on artificial intelligence and online distribution, which are two current hot topics. However, given there are few books available covering this topic it makes this a unique book and an excellent source of information.

Finally, some considerations on the technicality of the book. Medical writers new to the field will find the first five chapters interesting and helpful and may not feel that their lack of prior knowledge is a limit to their understanding. Seasoned medical writers with experience in this field will still find a lot of useful information in these and subsequent chapters (Chapters 6 to 9, particularly). Additional chapters (Chapters 10 to 15) provide advanced and rather technical information, which may not be immediately applicable to the daily writing projects of medical writers. These last chapters are definitely too technical for medical writers with no experience of medical devices.

Overall, the book goes into much detail and can get rather complex for a medical writer entering the field for the first time. A careful and thorough read is needed to profit from its content entirely. If you are among those writers who would benefit, you might consider using the book as a reference manual of where to go to answer queries, but not as a book to be read from A to Z.