THE FUTURE OF MEDICAL DEVICE REGULATION

Regulators have been more permissive for medical devices compared to their drug and biologic counterparts. While innovative products can thereby reach consumers more quickly, this approach raises serious public health and safety concerns. Additionally, the nature of medical devices is rapidly changing, as software has become as important as hardware. Regulation must keep pace with the current developments and controversies of this technology. This volume provides a multidisciplinary evaluation of the ethical, legal, and regulatory concerns surrounding medical devices in the United States and European Union. For medical providers, policymakers, and other stakeholders, the book offers a framework for the opportunities and challenges on the horizon for medical device regulation. Readers will gain a nuanced overview of the latest developments in patient privacy and safety, innovation, and new regulatory laws. This book is also available as Open Access on Cambridge Core.

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The Future of Medical Device Regulation

INNOVATION AND PROTECTION

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Glenn Cohen:
For Peter Barton Hutt, who taught me everything I know about FDA and much more.

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For my family.

Carmel Shachar:
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[1] Melyssa Eigen, Brian Brooks, and Nathan Rabb.