



Biomedical Software Regulation

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As health care professionals increasingly rely on biomedical software to help treat patients, it is also becoming increasingly complex. This book describes how the federal government is regulating the software used in delivering healthcare to millions of Americans. This user-friendly guide summarizes the key regulations promulgated by the Food and Drug Administration and the Center for Medicare and Medicaid Services (CMS) and provides several key reference materials and documents for use by professionals in a variety of healthcare settings. This landmark book covers a wide range of topics, including FDA regulation of software as a medical device; software validation; medical imaging software regulation; electronic recordkeeping; software used in clinical trials; laboratory information management systems (LIMS); and HIPAA privacy rules and security standards.



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