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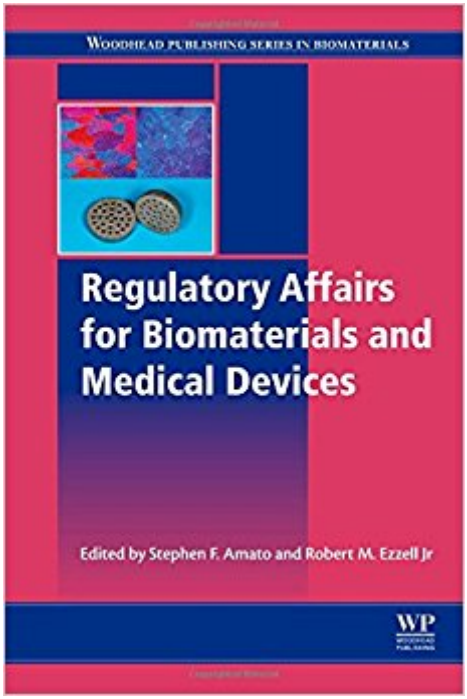

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Synopsis

All biomaterials and medical devices are subject to a long list of regulatory practises and policies which must be adhered to in order to receive clearance. This book provides readers with information on the systems in place in the USA and the rest of the world. Chapters focus on a series of procedures and policies including topics such as commercialization, clinical development, general good practise manufacturing and post market surveillance.Addresses global regulations and regulatory issues surrounding biomaterials and medical devicesEspecially useful for smaller companies who may not employ a full time vigilance professionalFocuses on procedures and policies including risk management, intellectual protection, marketing authorisation, university patent licenses and general good practise manufacturing

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Dr Amato teaches at Northeastern University, is a senior lecturer at Boston College and serves on the board of directors for several organizations, including BioSignostix, the Medical Development Group (MDG) and the Association of Graduate Regulatory Educators (AGRE). His research has been extensively published and he has presented on regulatory affairs across the United States, China and India.

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