1. Record Nr. UNINA9910786112503321 Autore Wong Jack Titolo Handbook of medical device regulatory affairs in Asia / / Jack Wong, Raymond K.Y. Tong Boca Raton, Fla.:,: CRC Press,, 2013 Pubbl/distr/stampa **ISBN** 0-429-07135-3 981-4411-22-1 Descrizione fisica 1 online resource (610 p.) Altri autori (Persone) TongRaymond (Raymond Kai-yu) Disciplina 610.284 Soggetti Medical instruments and apparatus - Safety regulations - Asia Medical instruments and apparatus - Standards Lingua di pubblicazione Inglese **Formato** Materiale a stampa Livello bibliografico Monografia Note generali Description based upon print version of record. Includes bibliographical references. Nota di bibliografia pt. 1. Introduction -- pt. 2. Medical device safety and related ISO Nota di contenuto standards -- pt. 3. Harmonization of medical devices in Asia -- pt. 4. Medical device regulatory system in the United States and the European Union -- pt. 5. Medical device regulatory system in Asia-Pacific region. Sommario/riassunto Medical device regulation in Asia has gained more importance than ever. Governments and regulatory bodies across the region have put in place new regulatory systems or refined the existing ones. A registered product requires a lot of technical documentation to prove its efficacy, safety, and quality. A smooth and successful registration process demands soft skills for dealing with various key stakeholders in the government, testing centers, and hospitals and among doctors.

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