1. Record Nr. UNINA9910822784403321 Autore Wong Jack Titolo Handbook of medical device regulatory affairs in Asia / / Jack Wong, Raymond K.Y. Tong Boca Raton, Fla., : Pan Stanford Pub., 2013 Pubbl/distr/stampa Boca Raton, Fla.:,: CRC Press,, 2013 **ISBN** 0-429-07135-3 981-4411-22-1 Edizione [1st ed.] 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. Nota di bibliografia Includes bibliographical references. Nota di contenuto pt. 1. Introduction -- pt. 2. Medical device safety and related ISO 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. Medical device regulation in Asia has gained more importance than Sommario/riassunto 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. Handbook of Medical Device Regulatory Affairs in Asia covers medical

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