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Sommario/riassunto	Written in a clear and concise style by an experienced author, this attractively-priced book covers regulatory affairs in all major global markets for pharmaceuticals and medical devices, making it the most comprehensive in its field.Following a look at drug development, complete sections are devoted to national and EU regulatory issues, manufacturing license application and retention, and regulation in the USA. Other topics dealt with include CDER, CBER and marketing and

manufacturing licenses, the ICH process and Good Laboratory/Clinical/Manufacturing Practices.Everything pharmacolog