1. Record Nr. UNINA9910677344203321 Autore Barrett Jeffrey S. Titolo Fundamentals of drug development / / Jeffrey S. Barrett Pubbl/distr/stampa Hoboken, New Jersey:,: Wiley,, [2022] ©2022 **ISBN** 1-119-91327-6 1-119-69173-7 1-119-69170-2 Descrizione fisica 1 online resource (512 pages) Disciplina 615.10724 Soggetti Pharmacology Lingua di pubblicazione Inglese **Formato** Materiale a stampa Livello bibliografico Monografia Nota di bibliografia Includes bibliographical references and index. Nota di contenuto The history of drug development -- The modern pharmaceutical industry: big and small pharma, biotechnology companies, and generic drug makers -- Legal considerations, intellectual property, patents and patent protection -- The global regulatory landscape -- Phases of drug development : old and new paradigms -- Discovery / preclinical --Phase I -- Phase II -- Phase IV, special populations and post marketing commitments -- Role and function of project teams --Compound progression and go / no go criteria -- Regulatory milestones and the submission process -- Life cycle management --Formulation development -- Chemistry and manufacturing (CMC) --Health economics and the healthcare industry -- Current state of affairs: attrition rates and evolving corporate strategies -- Medical devices -- Distribution and the supply chain -- Sales, marketing and advertising -- Generic drugs and the generic industry -- The generic approval process -- Data sharing and collaboration -- The future of the pharmaceutical industry. Sommario/riassunto "This book discusses how to conduct pharmaceutical research and the context for how the industry fits into global healthcare. Holistically, the well-qualified author helps readers and students of drug development

appreciate the time and expense of the process. Specifically, the work identifies the emerging trends shaping the future of drug development,

along with important related topics like generic drugs, data sharing, and collaboration. To aid in seamless reader comprehension, the book includes a glossary of terms and a self-assessment quiz for each chapter at the end. PowerPoint slides are also available as an online ancillary for adopting professors"--