

1. Record Nr.	UNINA9910829813403321
Autore	Weinberg Sandy <1950->
Titolo	Guidebook for drug regulatory submissions [[electronic resource] /] / Sandy Weinberg
Pubbl/distr/stampa	Hoboken, N.J., : John Wiley, c2009
ISBN	1-282-02803-0 9786612028038 0-470-45618-3 0-470-45617-5
Descrizione fisica	1 online resource (392 p.)
Disciplina	344.7304/233 344.7304233
Soggetti	Drugs - Law and legislation - United States Drug approval - United States
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 and index.
Nota di contenuto	Ten rules for drug regulatory submissions -- FDA meeting requests -- Orphan-drug applications -- Investigational new drug applications (INDs) -- New drug applications (NDAs) -- 505(b)2 new drug applications (NDAs) -- Abbreviated new drug applications (ANDAs) -- Annual reports -- International submissions / Carl A. Rockburne -- Future issues in regulatory submissions.
Sommario/riassunto	Destined to become every regulatory director's essential desktop companion professionals working to submit major documents to the Food and Drug Administration (FDA) are guaranteed to encounter numerous unexpected and daunting hurdles. Guidebook for Drug Regulatory Submissions offers a readable and clearly written road map for effective submission of documents for required regulatory reviews during drug development. Demystifying this complex, high-stakes process, author and nationally recognized drug regulation expert Sandy Weinberg presents professionals with authoritative tips, tool