Guidebook for drug regulatory submissions / Sandy Weinberg

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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, tools, and advice including suggestions for preparation, checklists for submission, an FDA evaluation tool for review, and copies of relevant FDA guidelines.
As well, vital information is provided on the most common types of submissions, including:
- Meeting Requests
- Orphan Drug Applications
- Investigatory New Drug Applications (INDAs)
- New Drug Applications (NDAs)
- 505(b)2 NDAs
- Abbreviated New Drug Applications (ANDAs)
- Annual Report
This reference also explores the pressures affecting the industry and the general public, as well as how these pressures will change the general nature and specific aspects of the submissions process over the near future. In addition, retired Canadian trade consul and regulatory consultant Carl Rockburne guest-authors a chapter comparing the FDA process to the four other major regulatory environments of Canada, the European Union, Japan, and Australia.