Guidebook for Drug Regulatory Submissions

Description: 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, 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 (INDs)
- New Drug Applications (NDs)
- 505(b)2 NDAs
- Abbreviated New Drug Applications (ANDs)
- 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.

Guidebook for Drug Regulatory Submissions is more than a useful guide; it is an essential tool to be kept on the desk of every regulatory director, submissions manager, vice president of Regulatory Affairs, and Food and Drug Administration reviewer responsible for the process of drug regulatory submissions.

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