Drug Development and Industrial Pharmacy, 33:701, 2007

ISSN: 0363-9045 print / 1520-5762 online
DOI: 10.1080/03639040600975048

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Book Review

Drug Products for Clinical Trials, Second Edition, Donald C. Monkhouse, Charles F. Carney, and James L. Clark, eds., Taylor & Francis Group, New York, NY, 2006. Hardback, 399 pages. ISBN-10: 0-8247-5462-X, ISBN-13: 978-0-8247-5462-4.

Drug Products for Clinical Trials, the second edition, covers the major changes seen in the operating environments of Clinical Trial Materials professionals (CTMPs) that have occured since publication of the first edition of this book. For example, new regulatory regions such as India and China have emerged. The implementation of radio frequency identification (RFID) and interactive voice response systems (IVRS) occurred. This most recent edition of the text discusses these and many other topics relevant to CTMPs.

The text begins by reviewing the evolving role of the CTMP, including a discussion of anti-counterfeiting techniques. Next, the authors present an overview of discovery and formulation trends. Issues related to physicochemical characterization and drug/device delivery systems receive coverage. Technical jargon that may be required when working with new dosage forms are introduced. Manufacturing and clinical medicine trends, ranging from new excipients to remote patient monitoring, are reviewed. Facility, personnel and handling requirements for developing, manufacturing and packaging potent and/or hazardous products are discussed. One author presents challenges unique to producing inhalation products for clinical trials. Another chapter provides an extensive discussion of clinical supply packaging and documentation, while another discusses the need and methods available for blinding various dosage forms.

The increased expectation to conduct international clinical trials creates the need for a global quality assurance program and this text reviews the requirements for conducting overseas trials and progress thus far made in harmonizing worldwide regulations. One chapter provides a useful checklist for working with vendors when outsourcing a product. Excellent ideas to keep training interesting and helpful tools for documenting a training program to meet regulatory requirements are also discussed. Finally, the authors present project management for the CTMP for various aspects of clinical trials.

The authors write succinctly and clearly and provide extensive references for further study. The goals of each chapter are clearly stated and the formatting allows one to easily find specific topics of interest. The text provides an excellent reference for new and experienced CTMPs, their managers, and the groups with which they interface.

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