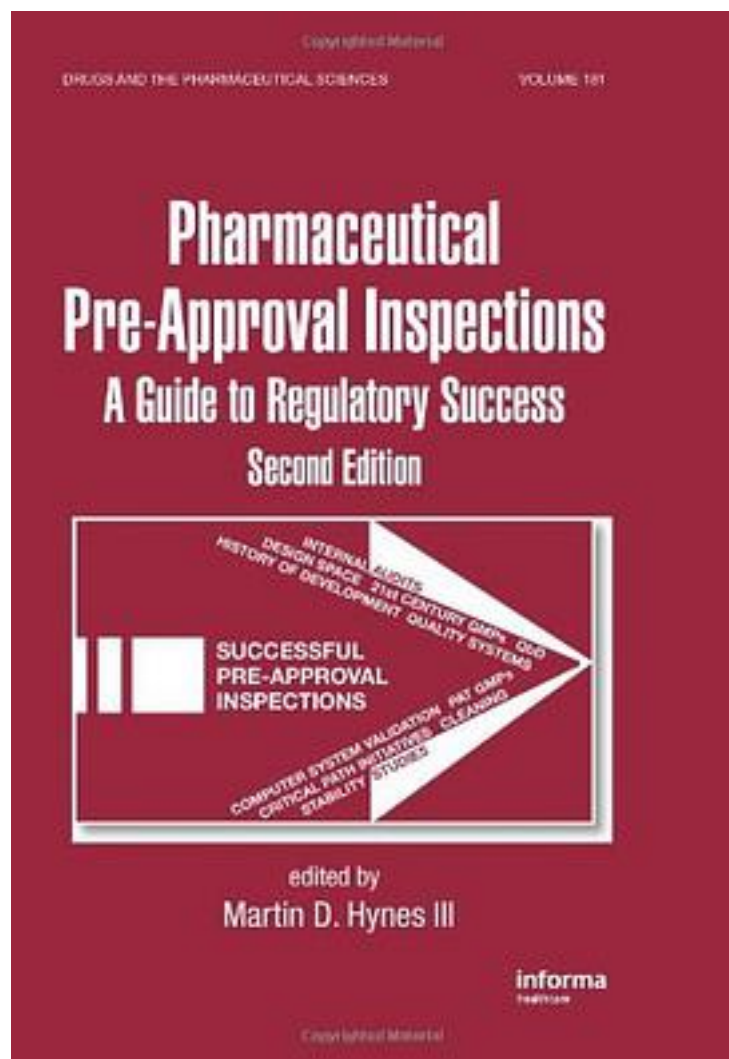


Preparing for FDA Pre-Approval Inspections



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This Second Edition is an essential guide to preparing for FDA pre-approval inspections-taking into account current trends in FDA expectations and inspection activities, such as the GMPs of the 21st Century, quality systems-based approach to inspections, risk-based inspections, quality by design, process analytical technology, design space, etc. The goal of this book is to help organizations gain rapid regulatory approval. Pharmaceutical Pre-Approval Inspections: A Guide to Regulatory Success, Second Edition: chronicles the major shifts in inspection activity as evidenced by a systems-based approach to inspections demonstrates what each area of pharmaceutical development, from research and development to training, is expected to provide to inspectors focuses on traditional development and submission activities, but also discusses cases where the transfer is from a domestic site to an international facility

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