



Preparing for FDA Pre-Approval Inspections: A Guide to Regulatory Success, Second Edition

(Drugs and the Pharmaceutical Sciences)

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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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