The Pharmaceutical Regulatory Process, Second Edition (Drugs and the Pharmaceutical Sciences)

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This Second Edition examines the mechanisms and means to establish regulatory compliance for pharmaceutical products and company practices. It focuses on major legislative revisions that impact requirements for drug safety reviews, product regulatory approvals, and marketing practices. Written by top industry professionals, practicing attorneys, and FDA regulators, it includes policies and procedures that pharmaceutical companies need to implement regulatory compliance post-approval.

New chapters cover:

- the marketing of unapproved new drugs and FDA efforts to keep them in regulatory compliance
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