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Active Pharmaceutical Ingredients: Development, Manufacturing, and Regulation (Drugs and the Pharmaceutical Sciences)

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Focusing on the three most critical components that successfully bring an API to market-process development, manufacturing, and governmental regulation and approval-this reference serves as a step-by-step guide to the planning and clear understanding of the bulk manufacturing of APIs. This guide offers current and timely discussions of the process development cycle, design engineering, the approval process, quality control and assurance, and validation, as well as plant manufacturing activities including materials management, maintenance, and safety.

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