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

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To successfully bring an Active Pharmaceutical Ingredient (API) to market, many steps must be followed to ensure compliance with governmental regulations. **Active Pharmaceutical Ingredients** is an unparalleled guide to the development, manufacturing, and regulation of the preparation and use of APIs globally.

Topics include:

- Safety, efficacy, and environmental/regulatory requirements
- Analysis of the recent movement of API manufacturing from the U.S. and Europe to countries such as India and China
- The FDA’s intensified foreign inspection program
- Multi-use and flexible design facilities
- The shift from maintenance scheduling to built-in reliability

This second edition focuses on the quality control regulations for APIs that have been added or amended since the first edition. These updates help ensure that pharmaceutical professionals and drug manufacturers meet the established and required guidelines set forth by the United States and international regulatory agencies.

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