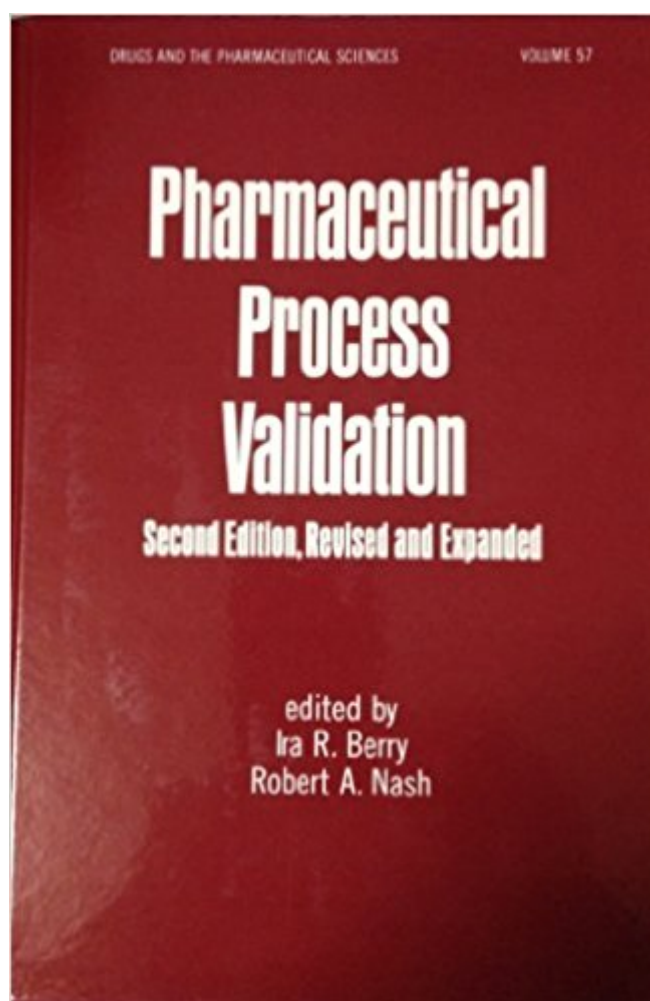




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Synopsis

The second edition of this text has been updated and enlarged to reflect current good manufacturing practice (CGMP) regulations and the increased interest in, and applicability of, process validation. "Pharmaceutical Process Validation" offers up-to-the-minute coverage of: regulations and validation; sterile process validation; organization in validation processes; solid dosage forms validation; raw material validation; analytical methods validation; and prospective and retrospective validation. Providing the contributions of leading experts in the field, the text also supplies examinations of current concepts in validation and new topics, such as: validation of cleaning systems and computer systems; equipment and water systems validation; and lyophilized and aerosol product validation.

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