Quality Assurance Compliance: Procedures for Pharmaceutical and Biotechnology Manufacturers

By Ira C. Peine

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Covering key areas of GMP compliance and QA, this text provides sample documentation and systems in use in pharmaceutical, biotechnology, and active pharmaceutical ingredient companies worldwide. Sixty-eight procedures with forms are grouped into eight critical areas: documentation, raw material control, in-process material control, corrective action, deviations and complaints, production cleaning, processing and documentation, QC lab documentation, product quality, and training and health. Fifty-eight forms, reports, and label formats enhance the practicality of the text. Most of the forms presented in the book are included on a diskette in ASCII format.

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