



Pharmaceutical Engineering Change Control

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Written especially for the pharmaceutical industry professional, this book addresses each part of the life-cycle of engineering change control. It covers issues in the EU and US and describes the operational requirements and responsibilities that ensure change controls are effectively applied and recorded. Providing guidance on how to demonstrate that a change control system is working, the book includes chapters on computer validation, customization of the change process to each project's needs, and case histories and anecdotes illustrate key points and provide a basis for change control training. It gives readers a toolbox for ensuring that adequate controls are implemented.

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