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within the industry It draws not only on this experience but on best practices and widely accepted conventions These practices and conventions are typically shaped by the demands of regulatory bodies and international organisations Chapters include Design Controls Validation Planning Risk Management Facilities and Utilities Validation Equipment and Software Validation Process Validation Packaging Validation Test Method Validation 21 CFR Part 11 Electronic Records Measurement Good Manufacturing Practices ISO 13485 Lean Basics Six Sigma Basics Polymer Processing Tools Useful References Page Count Over 200 pages

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