



# Computer Validation Compliance: A Quality Assurance Perspective

*Mary Ellen Double, Maryann McKendry*

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Computer Validation Compliance takes a systematic Quality Assurance (QA) approach to computer validation in a regulated environment. Built on the authors' experiences at major multinational pharmaceutical companies, this book presents a complete, step-by-step guide covering the QA role from early development to final completion, from a compliance/regulatory perspective. Topics include responsibilities of the user, the developer, and QA, vendor assessment, contract facilities, end user computing, and implementing a quality assurance program. Appendices include useful computer system validation sample documentation, a case study, and checklists.

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