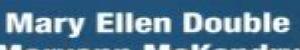
# Computer Validation Compliance

A Quality Assurance Perspective



Maryann McKendry



# <u>Computer Validation Compliance A Quality Assurance</u> <u>Perspective</u>

**Orlando Lopez** 

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Computer Validation Compliance Mary Ellen Double, Maryann McKendry, 1994-01-31 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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Compliance Handbook for Pharmaceuticals, Medical Devices, and Biologics Carmen Medina, 2003-12-09 This text lists the necessary steps for meeting compliance requirements during the drug development process It presents comprehensive approaches for validating analytical methods for pharmaceutical applications

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