

Computer Validation Compliance

A Quality Assurance Perspective



**Mary Ellen Double
Maryann McKendry**



Interpharm/CRC

Computer Validation Compliance A Quality Assurance Perspective

Carmen Medina



Computer Validation Compliance A Quality Assurance Perspective:

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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