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Covering regulatory requirements stipulated by the FDA, this book delineates the organization, planning, verification, and documentation activities and procedural controls required for compliance with worldwide computer systems validation regulations. The author introduces supporting technologies such as encryption and digital signatures and places regulatory compliance within the context of quality assurance. He demonstrates the importance of integrating validation activities into the system lifecycle using a structured top-down approach. He covers practical applications of quality assurance and engineering techniques as they relate to the development of systems fit to meet user and regulatory requirements.

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