1. Record Nr. UNINA9910877343903321 Autore Segalstad Siri H Titolo International IT regulations and compliance: quality standards in the pharmaceutical and regulated industries / / Siri H. Segalstad Chichester, West Sussex, United Kingdom, : Wiley, 2008 Pubbl/distr/stampa **ISBN** 1-282-34277-0 9786612342776 0-470-72182-0 0-470-72183-9 Descrizione fisica 1 online resource (340 p.) Disciplina 615/.19 Soggetti Pharmaceutical technology - Standards Pharmaceutical industry - Standards Pharmaceutical industry - Quality control Drugs - Standards Lingua di pubblicazione Inglese **Formato** Materiale a stampa Livello bibliografico Monografia Note generali Description based upon print version of record. Nota di bibliografia Includes bibliographical references and index. Nota di contenuto International IT Regulations and Compliance; Contents; Preface and Acknowledgements: 1 Quality Standards: 1.1 What Quality Is: 1.2 Mandatory and Voluntary Standards; 1.3 Pharmaceutical Industry Regulations; 1.4 US GxP Regulations; 1.5 European GxP Regulations; 1.6 Other GxP Regulations: 1.7 Good Manufacturing Practice: 1.8 Good Laboratory Practice; 1.9 Good Clinical Practice; 1.10 Medical Device Standards; 1.11 IT Systems in the GxP and Medical Device Regulations; 1.12 GAMP; 1.13 Mandatory Quality Standards in Other Industries; 1.14 Legal Issues; 1.15 The ISO; 1.16 The ASTM; 1.17 The IEEE 1.18 TasksReferences; 2 Regulatory Requirements for IT Systems; 2.1 Introduction; 2.2 US Requirements; 2.3 EU Requirements; 2.4 21 CFR Part 11; 2.5 The 'Part 11 Project'; 2.6 EU GMP Annex 11; 2.7 The PIC Document PI 011 Recommendation on Computerized Systems in Regulated 'GxP' Environments: 2.8 GAMP: 2.9 The ISO 9000 Series: 2.10 A Comparison between the Standards; 2.11 Conclusion; 2.12 Tasks;

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Sommario/riassunto

Standards, technologies, and requirements for computer validation have changed dramatically in recent years, and so have the interpretation of the standards and the understanding of the processes involved. International IT Regulations and Compliance brings together current thinking on the implementation of standards and regulations in relation to IT for a wide variety of industries. The book provides professionals in pharmaceutical and semiconductor industries with an updated overview of requirements for handling IT systems according to various Quality Standards and how to ?translate? these re