

# **Electronic Record Keeping**

**Achieving and Maintaining  
Compliance with 21 CFR Part 11  
and 45 CFR Parts 160, 162 and 164**



**David Nettleton  
Janet Gough**



Interpharm/CRC

# Electronic Record Keeping Achieving And Maintaining Compliance With 21 Cfr Part 11 And 45 Cfr Parts 160 162 And 164

**Fda (NA)**



## **Electronic Record Keeping Achieving And Maintaining Compliance With 21 Cfr Part 11 And 45 Cfr Parts 160 162 And 164:**

*Electronic Record Keeping* David Nettleton, Janet Gough, 2003-12-29 The current revolution in software and the regulations that have evolved to address it have increasingly caused companies to turn to off the shelf software for electronic record keeping Data captured in computerized systems must be as reliable if not more so than data on paper *Electronic Record Keeping Achieving Compliance with 21 CFR Part 11 and 45 CFR Parts 160 162 and 164* explores how to evaluate select implement and document an e system that will keep your organization in compliance Covering Title 21 of the Code of Federal Regulations CFR Part 11 and the parallel recently passed Title 45 CFR Parts 160 162 and 164 of the Health Insurance Portability and Accountability Act HIPAA this book provides guidance for selecting purchasing installing validating and managing commercial off the shelf software for data collection and retention It takes a number of years for industry standards for a new regulation to develop from dialog between companies and the regulating agency These standards are in place for Part 11 which was passed into law in 1997 Healthcare providers who must implement electronic record keeping can learn how to best do it by understanding the parallel between the new HIPAA regulations and the industry standards for Part 11 Further certain FDA driven activities such as patient record keeping in clinical trials now must comply with the new HIPAA regs as well To help companies achieve and maintain compliance the authors cover audit trails validation documentation training and security and accountability They discuss what the regulations say and what they mean Compliance may be mandatory but it also makes good business sense Companies that are compliant will always be poised to move forward and they will avoid the grief that comes from poor or faulty record keeping and documentation This book gives you the tools you need to keep your company both compliant and competitive Write It Down Janet Gough, 2005-03-30 A well understood tenet exists among the FDA and other regulatory bodies if you didn't write it down it didn't happen And if it didn't happen your company stands to lose time money and perhaps its competitive edge *Write it Down Guidance for Preparing Effective and Compliant Documentation* provides you with the tools you need to put effective **American Jurisprudence Proof of Facts, 3d Series**, 1988 Provides text and sample testimony to assist in preparing for and proving facts that may be in issue in judicial and administrative proceedings Kept up to date by packet supplements Library has second and third series **American Book Publishing Record**, 2004 **The British National Bibliography** Arthur James Wells, 2006 **Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures** International Society of Pharmaceutical Engineers, Parenteral Drug Association, 2001 *21 CFR Part 11* Orlando López, 2004-01-15 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 **Keys to**

**Electronic Record Compliance: CFR Part 11. Field Management Directive No. 146. Legal considerations in designing and implementing electronic processes. Guidance for agencies implementing electronic signature technologies. Recommendations for compliance with the Electronic Records Regulation. Computerized systems used in clinical trials. Final Rule: 21 CFR Part 11 ,2001** 21 CFR Orlando López,2004-01-15 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 *Good Practice and Compliance for Electronic Records and Signatures, Part 3* PDA,2004-10 This document is intended for technology professionals performing activities related to computer systems subject to 21 CFR Part 11 Activities include specification acquisition development modification and maintenance Systems subject to 21 CFR Part 11 include computer systems and networks which 1 create Electronic Records or Electronic Signatures ER ES 2 maintain ER ES records 3 transmit ER ES records and 4 modify ER ES or have the potential to adversely affect the integrity of ER ES **Title 21 CFR Part** Fda (NA),2005-01-30 11 210 211 ERES Drug GMP s Electronic Records and Electronic Signatures Forum Paul Irving,2002-12 This forum provides an opportunity to read and share the views of experts and non experts in regard to electronic records electronic signatures 21 CFR Part II and all associated components in pharmaceutical manufacturing The amount of paper created by the regulatory requirements for FDA and MCA compliance necessitates a more focussed approach to the electronic issues associated with validation

**Fda 21 Cfr Part 11** Catherine W. Reddick,2002 **21 CFR Part 11 Pocket Guide** Fda,2005-01-30 21 CFR Part 11 Electronic Records Signatures ERES w Scope and Applications Electronic Records and Electronic Signatures Forum Trevor Deeks,2002-07 This text looks at electronic records and electronic signatures and considers the amount of paperwork created by the regulatory requirements for FDA and MCA compliance so necessitating a more focussed approach to the electronic issues associated with validation **Title 21 Cfr Part 11 a Complete Guide - 2019 Edition** Gerardus Blokdyk,2019-03-18 Have new functions been added that could impact the integrity and accuracy of electronic records What is the duration of use and how does it relate to the expiration date What are the benefits of electronic signatures and record keeping Do you provide training to your staff on how to use the system How frequently must you back up data generated by the system Defining designing creating and implementing a process to solve a challenge or meet an objective is the most valuable role In EVERY group company organization and department Unless you are talking a one time single use project there should be a process Whether that process is managed and implemented by humans AI or a combination of the two it

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## The Enigmatic Realm of **Electronic Record Keeping Achieving And Maintaining Compliance With 21 Cfr Part 11 And 45 Cfr Parts 160 162 And 164**: Unleashing the Language is Inner Magic

In a fast-paced digital era where connections and knowledge intertwine, the enigmatic realm of language reveals its inherent magic. Its capacity to stir emotions, ignite contemplation, and catalyze profound transformations is nothing short of extraordinary. Within the captivating pages of **Electronic Record Keeping Achieving And Maintaining Compliance With 21 Cfr Part 11 And 45 Cfr Parts 160 162 And 164** a literary masterpiece penned by a renowned author, readers set about a transformative journey, unlocking the secrets and untapped potential embedded within each word. In this evaluation, we shall explore the book's core themes, assess its distinct writing style, and delve into its lasting effect on the hearts and minds of those that partake in its reading experience.

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