

Overview of the main differences between 21 CFR Part 11 and EU GMP Annex 11

ASPECT	21 CFR PART 11	EU GMP ANNEX 11
Purpose	Provides criteria for electronic records, electronic signatures, and handwritten signatures, which are captured for an electronic record.	Provides guidance to the EMA GMP's industry criteria for effective implementation, validation, use, control, and maintenance of computerized systems.
Scope	Applies to electronic records, electronic signatures, and handwritten signatures executed to electronic records that are created, modified, maintained, archived, retrieved, or transmitted, under FDA regulations.	Applies to all forms of computerized systems used as part of a GMP regulated activities within the EU. Does not apply to medical device software. It may be applicable to software used in the production of a device and software used in implementation of the device manufacturer's Quality system.
Applicability	Applies to drug, biotechnology, and medical equipment manufacturers in FDA-regulated industries, including electronic submissions to the FDA.	Intended to ensure product Quality, process control, or QA when a computerized system replaces manual operations.
Legal	Legal requirement issued by the FDA. Applicable to FDA-regulated industries.	Not a legal requirement; it is a guideline in the context of the EMA GMPs. However, it is mandatory on each national level in the EU and therefore essential for compliance with related EU regulations.
Overarching Structure	Subpart A: General Provisions 11.1 Scope 11.2 Implementation 11.3 Definitions Subpart B - Electronic Records 11.10 Controls for closed systems 11.30 Controls for open systems 11.50 Signature manifestations 11.70 Signature/record linking Subpart C - Electronic Signatures 11.100 General requirements 11.200 Electronic signature components and controls 11.300 Controls for identification codes/passwords	Consists of four sections: - General guidance - Project phase - Operational phase - Glossary
Key Terminology	- Electronic record - Electronic signature - Digital signature - Handwritten signature - Closed system - Open system	- Electronic signature - Computerized system - Accuracy checks - Audit trail - Data storage - Printouts - Change Management - Periodic evaluation

Eu Gmp Guide Annex 11

Roman Wölfel

A red circular graphic with a gradient, appearing as a stylized arrow or a partial circle, located to the right of the author's name.

Eu Gmp Guide Annex 11:

EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP Orlando Lopez, 2015-04-06 Good Manufacturing Practice GMP ensures medicinal products are produced consistently and controlled to the quality standards appropriate for their intended use and as required by product specifications or marketing authorization Annex 11 details the European Medicines Agency EMA GMP requirements for computer systems The purpose of Annex 11 is

Ensuring the Integrity of Electronic Health Records Orlando López, 2020-12-21 Data integrity is a critical aspect to the design implementation and usage of any system which stores processes or retrieves data The overall intent of any data integrity technique is the same ensure data is recorded exactly as intended and upon later retrieval ensure the data is the same as it was when originally recorded Any alternation to the data is then traced to the person who made the modification The integrity of data in a patient's electronic health record is critical to ensuring the safety of the patient This book is relevant to production systems and quality control systems associated with the manufacture of pharmaceuticals and medical device products and updates the practical information to enable better understanding of the controls applicable to e records The book highlights the e records suitability implementation and associated risk assessed controls and e records handling The book also provides updated regulatory standards from global regulatory organizations such as MHRA Medicines and Healthcare Products Regulatory Agency UK FDA Food and Drug Administration US National Medical Products Association China TGA Therapeutic Goods Administration Australia SIMGP Russia State Institute of Medicines and Good Practices and the World Health Organization to name a few Data Integrity in Pharmaceutical and Medical Devices Regulation

Operations Orlando Lopez, 2016-11-03 Data integrity is fundamental in a pharmaceutical and medical devices quality system This book provides practical information to enable compliance with data integrity while highlighting and efficiently integrating worldwide regulation into the subject The ideas presented in this book are based on many years experience in regulated industries in various computer systems development maintenance and quality functions In addition to case studies a practical approach will be presented to increase efficiency and to ensure that the design and testing of the data integrity controls are correctly achieved **Pharmaceutical and Medical Devices Manufacturing Computer Systems**

Validation Orlando Lopez, 2018-10-02 Validation of computer systems is the process that assures the formal assessment and report of quality and performance measures for all the life cycle stages of software and system development its implementation qualification and acceptance operation modification requalification maintenance and retirement PICS CSV PI 011 3 It is a process that demonstrates the compliance of computer systems functional and non functional requirements data integrity regulated company procedures and safety requirements industry standards and applicable regulatory authority's requirements Compliance is a state of being in adherence to application related standards or conventions or regulations in laws and similar prescriptions This book which is relevant to the pharmaceutical and medical devices regulated operations

provides practical information to assist in the computer validation to production systems while highlighting and efficiently integrating worldwide regulation into the subject A practical approach is presented to increase efficiency and to ensure that the validation of computer systems is correctly achieved *Data Integrity and Data Governance* Robert D

McDowall,2018-11-06 Data integrity is the hottest topic in the pharmaceutical industry Global regulatory agencies have issued guidance after guidance after guidance in the past few years most of which does not offer practical advice on how to implement policies procedures and processes to ensure integrity These guidances state what but not how Additionally key stages of analysis that impact data integrity are omitted entirely The aim of this book is to provide practical and detailed help on how to implement data integrity and data governance for regulated analytical laboratories working in or for the pharmaceutical industry It provides clarification of the regulatory issues and trends and gives practical methods for meeting regulatory requirements and guidance Using a data integrity model as a basis the principles of data integrity and data governance are expanded into practical steps for regulated laboratories to implement The author uses case study examples to illustrate his points and provides instructions for applying the principles of data integrity and data governance to individual laboratory needs This book is a useful reference for analytical chemists and scientists management and senior management working in regulated laboratories requiring either an understanding about data integrity or help in implementing practical solutions Consultants will also benefit from the practical guidance provided Practical

Pharmaceutics Paul Le Brun,Sylvie Crauste-Manciet,Irene Krämer,Julian Smith,Herman Woerdenbag,2023-06-15 Practical Pharmaceutics contains essential knowledge on the preparation quality control logistics dispensing and use of medicines It features chapters written by experienced pharmacists and scientists working in hospitals academia and industry throughout Europe including practical examples as well as information on current GMP and GMP based guidelines and EU legislation In this second edition all chapters have been updated with numerous new as well as didactically revised illustrations and tables A completely new chapter about therapeutic proteins and Advanced Therapy Medicinal Products was added From prescription to production from usage instructions to procurement and the impact of medicines on the environment the book provides step by step coverage that will help a wide range of readers students as well as professionals It offers product knowledge for all pharmacists working directly with patients and it will enable them to make the required medicine available to store medicines properly to adapt medicines if necessary and to dispense medicines with the appropriate information for patients as well as caregivers about product care and how to maintain the quality of the product The basic knowledge presented in the book will also be valuable for industrial pharmacists to remind and focus them on the application of the medicines manufactured The basic and practical knowledge on the design preparation and quality management of medicines can directly be applied by the pharmacists whose main duty is production in community and hospital pharmacies and in industry Undergraduate as well as graduate pharmacy students will find knowledge presented in a coherent way and fully

supported with relevant examples Practical Pharmaceutics has become a reliable and recognised source for the acquisition of pharmaceutical technological knowledge The book is used in the curriculum of a number of international universities and schools of Pharmacy *Pharmaceutical Microbiological Quality Assurance and Control* David Roesti, Marcel

Goverde, 2020-01-02 Relying on practical examples from the authors experience this book provides a thorough and modern approach to controlling and monitoring microbial contaminations during the manufacturing of non sterile pharmaceuticals Offers a comprehensive guidance for non sterile pharmaceuticals microbiological QA QC Presents the latest developments in both regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors experience in globalized pharmaceutical companies and expert networks **Pharmaceutical Computer Systems Validation** Guy

Wingate, 2016-04-19 Thoroughly revised to include the latest industry developments the Second Edition presents a comprehensive overview of computer validation and verification principles and how to put them into practice To provide the current best practice and guidance on identifying and implementing improvements for computer systems the text extensively reviews regulations of pharmaceuticals healthcare products blood processing medical devices clinical systems and biotechnology Ensuring that organizations transition smoothly to the new system this guide explains how to implement the new GMP paradigm while maintaining continuity with current practices In addition all 24 case studies from the previous edition have been revised to reflect the new system *Validation of Chromatography Data Systems* Robert D

McDowall, 2016-11-23 Guiding chromatographers working in regulated industries and helping them to validate their chromatography data systems to meet data integrity business and regulatory needs This book is a detailed look at the life cycle and documented evidence required to ensure a system is fit for purpose throughout the lifecycle Initially providing the regulatory data integrity and system life cycle requirements for computerised system validation the book then develops into a guide on planning specifying managing risk configuring and testing a chromatography data system before release This is followed by operational aspects such as training integration and IT support and finally retirement All areas are discussed in detail with case studies and practical examples provided as appropriate The book has been carefully written and is right up to date including recently released FDA data integrity guidance It provides detailed guidance on good practice and expands on the first edition making it an invaluable addition to a chromatographer s book shelf *Good Informatics Practices (GIP) Module: Infrastructure and Cloud* Jeffrey Guo, David Jemmett, John Minarovich, Vince Ricco, John Ruehle CPHIMS, MBA,, Dan Stellick, Bob Sturm, MBA, DeEtte Trubey, PMP, Ford Winslow, 2013

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Table of Contents Eu Gmp Guide Annex 11

1. Understanding the eBook Eu Gmp Guide Annex 11
 - The Rise of Digital Reading Eu Gmp Guide Annex 11
 - Advantages of eBooks Over Traditional Books
2. Identifying Eu Gmp Guide Annex 11
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Eu Gmp Guide Annex 11
 - User-Friendly Interface
4. Exploring eBook Recommendations from Eu Gmp Guide Annex 11
 - Personalized Recommendations
 - Eu Gmp Guide Annex 11 User Reviews and Ratings
 - Eu Gmp Guide Annex 11 and Bestseller Lists
5. Accessing Eu Gmp Guide Annex 11 Free and Paid eBooks
 - Eu Gmp Guide Annex 11 Public Domain eBooks
 - Eu Gmp Guide Annex 11 eBook Subscription Services
 - Eu Gmp Guide Annex 11 Budget-Friendly Options
6. Navigating Eu Gmp Guide Annex 11 eBook Formats

- ePub, PDF, MOBI, and More
- Eu Gmp Guide Annex 11 Compatibility with Devices
- Eu Gmp Guide Annex 11 Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Eu Gmp Guide Annex 11
 - Highlighting and Note-Taking Eu Gmp Guide Annex 11
 - Interactive Elements Eu Gmp Guide Annex 11
- 8. Staying Engaged with Eu Gmp Guide Annex 11
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Eu Gmp Guide Annex 11
- 9. Balancing eBooks and Physical Books Eu Gmp Guide Annex 11
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Eu Gmp Guide Annex 11
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Eu Gmp Guide Annex 11
 - Setting Reading Goals Eu Gmp Guide Annex 11
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Eu Gmp Guide Annex 11
 - Fact-Checking eBook Content of Eu Gmp Guide Annex 11
 - Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
- 14. Embracing eBook Trends
 - Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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