

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: <ul style="list-style-type: none"> - General guidance - Project phase - Operational phase - Glossary |
| Key Terminology | <ul style="list-style-type: none"> - Electronic record - Electronic signature - Digital signature - Handwritten signature - Closed system - Open system | <ul style="list-style-type: none"> - Electronic signature - Computerized system - Accuracy checks - Audit trail - Data storage - Printouts - Change Management - Periodic evaluation |

Eu Gmp Guide Annex 11

**Ford Winslow, Roger Fraumann,
CISSP, Robert Sturm, MBA, DeEtte
Trubey, PMP**

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

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

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

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 **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 **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 **Validation of Chromatography Data Systems** R. D. McDowall,2005 This title

introduces the basics of computer validation It is ideal for the chromatographer and will be welcomed by consultants or those in regulatory agencies **Good Informatics Practices (GIP) Module: Risk Management** Ford Winslow, Roger

Fraumann, CISSP, Robert Sturm, MBA, DeEtte Trubey, PMP, WHO Expert Committee on Specifications for

Pharmaceutical Preparations World Health Organization, 2019-05-29 The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear independent and practical standards and guidelines for the quality assurance of medicines Standards are developed by the Committee through worldwide consultation and an international consensusbuilding process The following new guidelines were adopted and recommended for use Procedure for development of the WHO medicines quality assurance guidelines Guidelines on Good Manufacturing Practices GMP for heating ventilation and air conditioning systems HVAC illustrative part Guidance on GMP for Validation including the general main text analytical procedure validation validation of computerized systems and qualification in the area of interchangeability of multisource medicines the Protocol to conduct equilibrium solubility experiments for the purpose of biopharmaceutics classification systembased classification of active pharmaceutical ingredients for biowaiver Guidelines on Import Procedures for pharmaceutical products and the Good Practice Guidance document on implementing the collaborative procedures All of the above are included in this report and recommended for implementation **Automation and Validation of**

Information in Pharmaceutical Processing Joseph F. deSpautz, 1998-06-16 This thoroughly authoritative work furnishes organizational technological validation project management and business perspectives on pharmaceutical information automation from industry and system automation professionals demonstrating how to fulfill computer system validation requirements for hardware applications networks data center operat *Clinical Data Management: A Comprehensive Guide to Best Practices 2025* Author:1- LAKSHMI PRIYA DARSHINI PULAVARTHI Author:2- DR. S SRINIWAS, PREFACE Clinical data management serves as the cornerstone of modern therapeutic development ensuring that every datum collected curated and analyzed faithfully represents the patient experience and underpins sound scientific conclusions In Clinical Data Management A Comprehensive Guide to Best Practices we embark on a journey that begins with the fundamental principles of data integrity quality assurance and regulatory compliance and progresses through the hands on execution of study setup database design coding conventions and query management This guide is written for the clinical research professional who seeks both high level insight and practical actionable guidance whether you are designing your first case report form implementing an electronic data capture system or harmonizing data from multiple global sites Drawing upon decades of industry experience and lessons learned from regulatory inspections and real world trials we illuminate the processes that safeguard patient safety and ensure the credibility of trial outcomes from the meticulous mapping of protocol requirements to database specifications through risk based monitoring strategies and vendor oversight to the final lock and archival of the clinical database Along the way you will find clear explanations of industry standards such as CDISC s SDTM and ADaM models ICH E6 R3 guidance and evolving trends in real world evidence and decentralized trials Each chapter highlights best practices common pitfalls and emerging technologies such as automation in data cleaning AI driven query resolution and blockchain for audit trails so that you can adopt innovations without compromising compliance Whether you lead a small data

management team or oversee enterprise wide operations this book empowers you to establish robust governance optimize workflows and foster a culture of continuous improvement By the end of this guide you will not only master the technical toolkit required for modern clinical data management but also appreciate how rigorous data practices translate into faster study timelines cost savings and ultimately more reliable evidence to guide patient care It is our hope that this work becomes your trusted companion in the pursuit of excellence helping you to navigate complexity with confidence and to deliver on the promise of data driven innovation in clinical research Authors [The Startup Protocol](#) Sally Ann Frank,2024-03-01 There are lots of founders and lots of ideas floating around to help improve the delivery of healthcare services and positively affect the health of each of us as individuals as well as groups of patients afflicted by chronic or acute diseases Unfortunately many of these ideas never reach their full potential to improve patient outcomes or reduce costs of care Sometimes it s because the idea isn t feasible or scalable Sometimes it s because the market isn t ready or regulators aren t ready And sometimes it s just because the founder or founding team has a blind spot or two Not only do these hidden blind spots ensure their failure but in many cases with better planning or a greater more holistic understanding of the market forces the blind spot can be overcome Or better yet the founder can realize that their idea is doomed from the start and consider other better options to solve the problem they are attacking The goal of this book is to help founders and their teams identify blind spots and avoid the most common pitfalls of starting a digital health company Having spent time with founders VC companies and most importantly prospective digital health startups patterns have emerged regarding those startups that are successful and those that die an often slow and painful death While not a recipe for guaranteed success having a guidebook of sorts can help navigate the perils associated with building a digital health company and can very likely improve the odds of success The book will go through the typical life cycle of an early stage company from ideation to the first few customer deals and highlight best practices for tackling the challenges at each stage including What problem are you trying to solve And why are you trying to solve this problem Who will help you build the solution and company How will you build the solution How will you pitch your company How will you sell your solution And what does success look like to you your stakeholders and your customers

Method Validation in Pharmaceutical Analysis Joachim Ermer,Phil W. Nethercote,2025-03-06 New edition of the gold standard in the field of pharmaceutical analysis extensively updated to include the new ICH Guidelines Q2 R2 and Q14 Following a holistic lifecycle approach to analytical procedures *Method Validation in Pharmaceutical Analysis* provides hands on information for readers involved in development validation and continued maintenance and evaluation of analytical procedures in pharmaceutical analysis This newly revised and updated Third Edition includes much needed interpretation of the most recent ICH guidelines for validation and method development as well as recent publications of the USP on Analytical Procedure Lifecycle Management and the activities of the British Pharmacopeia AQbD Working Party It also addresses hot topics in the field such as data integrity and continuous monitoring of analytical performance Written by a

team of highly qualified pharmaceutical professionals Method Validation in Pharmaceutical Analysis includes information on relevant topics such as Data governance data integrity and data quality as well as analytical instrument qualification and system validation lifecycle and continued HPLC performance qualification Analytical target profile decision rules and fitness for intended use and performance characteristics of analytical procedures Method selection development and optimization multivariate analytical procedures and risk assessment and analytical control strategy Implementation of compendial pharmacopeia test procedures transfer of analytical procedures and a lifecycle approach to transfer of analytical procedures Completely comprehensive in coverage Method Validation in Pharmaceutical Analysis is an essential reference for scientists researchers and professionals in the pharmaceutical industry analytical chemists QC and QA staff and public authorities tasked with relevant regulatory responsibilities

Drugs Rick Ng, 2015-04-13 The third edition of this best selling book continues to offer a user friendly step by step introduction to all the key processes involved in bringing a drug to the market including the performance of pre clinical studies the conduct of human clinical trials regulatory controls and even the manufacturing processes for pharmaceutical products Concise and easy to read *Drugs From Discovery to Approval Third Edition* quickly introduces basic concepts then moves on to discuss target selection and the drug discovery process for both small and large molecular drugs The third edition incorporates the latest developments and updates in the pharmaceutical community provides more comprehensive coverage of topics and includes more materials and case studies suited to college and university use Biotechnology is a dynamic field with changes across R D clinical trials manufacturing and regulatory processes and the third edition of the text provides timely updates for those in this rapidly growing field

Handbook of Radiopharmaceuticals Michael R. Kilbourn, Peter J. H. Scott, 2021-01-05 The thoroughly updated new edition of the authoritative reference in Radiopharmaceutical Sciences The second edition of *Handbook of Radiopharmaceuticals* is a comprehensive review of the field presenting up to date coverage of central topics such as radionuclide production synthetic methodology radiopharmaceutical development and regulations and a wide range of practical applications A valuable reference work for those new to the Radiopharmaceutical Sciences and experienced professionals alike this volume explores the latest concepts and issues involving both targeted diagnostic and therapeutic radiopharmaceuticals Contributions from a team of experts from across sub disciplines provide readers with an immersive examination of radiochemistry nuclear medicine molecular imaging and more Since the first edition of the *Handbook* was published Nuclear Medicine and Radiopharmaceutical Sciences have undergone major changes New radiopharmaceuticals for diagnosis and therapy have been approved by the FDA the number of clinical PET and SPECT scans have increased significantly and advances in Artificial Intelligence have dramatically improved research techniques This fully revised edition reflects the current state of the field and features substantially updated and expanded content New chapters cover topics including current Good Manufacturing Practice cGMP regulatory oversight novel approaches to quality control ensuring that readers are informed of

the exciting developments of recent years This important resource Features extensive new and revised content throughout Covers key areas of application for diagnosis and therapy in oncology neurology and cardiology Emphasizes the multidisciplinary nature of Radiopharmaceutical Sciences Discusses how drug companies are using modern radiopharmaceutical imaging techniques to support drug discovery Examines current and emerging applications of Positron Emission Tomography PET and Single Photon Emission Computed Tomography SPECT Edited by recognized experts in radiochemistry and PET imaging Handbook of Radiopharmaceuticals Radiochemistry and **CSV Essentials** Ludovico Dragoni,2023-10-24 In the dynamic world of pharmaceutical technology ensuring the safety efficacy and quality of products is more important than ever At the intersection of technological innovation and strict regulatory compliance lies computer system validation CSV an essential but often misunderstood element This volume is an indispensable guide to navigating the intricate facets of CSV and outlines the most important aspects of CSV with clarity and precision Discussed are the regulatory foundations exploration of the main players and involved processes key concepts of validation risk based approach up to future projections and the incorporation of emerging technologies Finally practical advice drawn from my own experience will also be provided including resources blogs and websites that I have found extremely useful Whether you are starting from scratch and want a solid foundation or are already familiar with the subject but want to fill in some gaps this book will provide you with a comprehensive and detailed overview of the world of CSV

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