SAP – GMP Compliance and Validation

30-31 October 2012, Vienna, Austria

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LEARNING OBJECTIVES:

- GMP: Where do we come from – where do we go?
- Validation:
  - Validation strategies
  - What needs to be validated?
  - Global versus local
  - User requirements
  - Risk management
- Operation
  - Change management
  - Lifecycle management
  - Security and authorisation concepts
  - Periodic evaluation
- SAP Solution manager
- E-records and E-signatures within SAP

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EUROPEAN COMPLIANCE ACADEMY

Sap Validation And Gmp Compliance

C Cleary

Sap Validation And Gmp Compliance:

Validating Corporate Computer Systems Guy Wingate,2000-05-31 One of the biggest computer validation challenges facing pharmaceutical manufacturers is the large corporate system This book provides practical information and advice on good IT practice and validation principles Written by experts it includes case studies on EDMSs EAM systems LIMSs and MRP II systems **Auditing and GRC Automation in SAP** Maxim Chuprunov,2013-04-09 Over the last few years financial statement scandals cases of fraud and corruption data protection violations and other legal violations have led to numerous liability cases damages claims and losses of reputation As a reaction to these developments several regulations have been issued Corporate Governance the Sarbanes Oxley Act IFRS Basel II and III Solvency II and BilMoG to name just a few In this book compliance is understood as the process mapped not only in an internal control system that is intended to guarantee conformity with legal requirements but also with internal policies and enterprise objectives in particular efficiency and profitability The current literature primarily confines itself to mapping controls in SAP ERP and auditing SAP systems Maxim Chuprunov not only addresses this subject but extends the aim of internal controls from legal compliance to include efficiency and profitability and then well beyond because a basic understanding of the processes involved in IT supported compliance management processes are not delivered along with the software Starting with the requirements for compliance Part I he not only answers compliance relevant questions in the form of an audit guide for an SAP ERP system and in the form of risks and control descriptions Part II but also shows how to automate the compliance management process based on SAP GRC Part III He thus addresses the current need for solutions for implementing an integrated GRC system in an organization especially focusing on the continuous control monitoring topics Maxim Chuprunov mainly targets compliance experts auditors SAP project managers and consultants responsible for GRC products as readers for his book They will find indispensable information for their daily work from the first to the last page In addition MBA management information system students as well as senior managers like CIOs and CFOs will find a wealth of valuable information on compliance in the SAP ERP environment on GRC in general and its implementation in particular **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 **Testing SAP R/3** Jose Fajardo,Elfriede Dustin,2007-04-10 Testing SAP R 3 A Manager s Step by Step Guide shows how to implement a disciplined efficient and proven approach for testing SAP R 3 correctly from the beginning of the SAP implementation through post production support The book also shows SAP professionals how to efficiently provide testing coverage for all SAP objects before they are moved into a production environment Computer Systems Validation Guy Wingate,2003-12-18 Both

pervasive and ubiquitous computerized systems are now an integral component of every corporate strategy in pharmaceutical and healthcare companies However when technology is combined with high risk public safety projects or the production and control of life saving medicines or devices it is necessary to ensure that it is reliable quality *GMP Compliance, Productivity, and Quality* Vinay Bhatt,1998-06-30 Written by twenty eight experts filled with recommendations that can immediately be put into action this book provides the strategies and tactics required to link and harmonize manufacturing processes with GMP to achieve optimum operability and cost effective regulatory compliance Drawn from name brand and generic companies and regulatory and co *Fundamental and Applied Aspects of Animal Cell Cultivation* J. P. Barford,1995 The advent of modern biological techniques such as hybridoma technology recombinant DNA techniques and viral transformation of cells has made the continuous production of a wide variety of biologicals possible using animal cells The use of such products is well established in many diagnostic and increasingly therapeutic applications the U S market for antibodies for example has been projected to increase from a 1991 level of US 0 33 billion to 1998 level of US 3 8 billion Total sales of such products in 1992 was US 4 2 billion The increasing application of this technology depends on increasing the efficiency of production and bioseparation and addressing various safety issues This book examines the fundamental and applied aspects of animal cell cultivation **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 *Handbook of Research on Emerging Technologies for Effective Project Management* Jamil, George Leal,Ribeiro, Fernanda,Malheiro da Silva, Armando,Maravilhas Lopes, Sérgio,2019-09-13 Driven by such tools as big data cognitive computing new business models and the internet of things the overall demand for innovation is becoming more critical for competitiveness and emerging technologies These technologies have become real alternatives for the market and offer new perspectives for modern project management applications The Handbook of Research on Emerging Technologies for Effective Project Management is an essential research publication that proposes innovations for firms and markets through the exploration of project management principles and methods and the effective integration of knowledge and innovation It encompasses academic and scientific propositions reviews for conceptual bases applications of theories in new market solutions and cases of successful insertion of disruptive technologies and business models in new competitive market offers Featuring a range of topics such as innovation management business administration and marketing this book is ideal

for project managers IT specialists software developers executives practitioners managers marketers researchers and industry professionals *Code of Federal Regulations* ,2009 Special edition of the Federal register containing a codification of documents of general applicability and future effect as of with ancillaries **Data Management, Analytics and Innovation** Saptarsi Goswami,Inderjit Singh Barara,Amol Goje,C. Mohan,Alfred M. Bruckstein,2022-09-21 This book presents the latest findings in the areas of data management and smart computing big data management artificial intelligence and data analytics along with advances in network technologies The book is a collection of peer reviewed research papers presented at Sixth International Conference on Data Management Analytics and Innovation ICDMAI 2022 held virtually during January 14 16 2022 It addresses state of the art topics and discusses challenges and solutions for future development Gathering original unpublished contributions by scientists from around the globe the book is mainly intended for a professional audience of researchers and practitioners in academia and industry *Pharma's Prescription* Kamal Biswas,2013-10-21 The pharmaceutical industry needs a shot in the arm and not a moment too soon The executive suite is mired in a bygone era a time when extensive well funded pharmaceutical R D produced blockbuster drugs kept everything in house and reaped the financial rewards But that way of working needs to change Executives now need to know what the technologists in their companies are doing in order to survive the next decade Written for those new to industry as well as for experienced professionals or specialists looking to expand their knowledge this book is a must read for business executives and information technologists alike Pharma s Prescription bridges the knowledge gap between current business practices and the most valuable technologies today This book is filled with practical real life examples from industry and is a straightforward guide for all pharmaceutical and information technology executives who need to improve their businesses Focuses on practical solutions that are easily incorporated in your day to day work Integrates business operations and information technology Highlights the industry s top turn around stories Discusses pharmaceutical industry trends growth opportunities innovation drivers regulatory complexities and emerging market operations **Protecting the Nation's Blood Supply from Infectious Agents** United States. Congress. House. Committee on Government Reform and Oversight. Subcommittee on Human Resources and Intergovernmental Relations,1996 **New Scientist** ,2000 Handbook of Spices in India: 75 Years of Research and Development P N Ravindran,K Sivaraman,S Devasahayam,K Nirmal Babu,2024-06-24 This compendium presents comprehensive information on more than 25 important spice crops commercially grown in India and traded globally apart from over 40 spices that have the potential to be popularized In 70 chapters the book covers the achievements in research and development made in India for the past 75 years in various organizations including research institutes agricultural universities and private sector laboratories Spices are natural products of plant origin used primarily for flavouring and seasoning or for adding pungency and flavour to foods and beverages The flavour and fragrance of Indian spices had a magic spell on human culture since very ancient days The importance of spices in Indian life and its contribution

to the economy are substantial India as the world s leading producer of spices is also a significant stakeholder in spices export trade globally Indian spices being sources of many high value compounds are also gaining muchimportance for other diversified uses especially for their pharmaceutical and nutraceutical properties A wide variety of 52 spices are grown in India including black pepper chillies cardamom ginger turmeric cinnamon nutmeg garlic onion cumin coriander saffron and vanilla This book complies a comprehensive holistic review on the subject written by the best experts in the field in India representing diverse agencies This book is a single point reference book for all those involved in the research study teaching and use of spices in India and abroad **Medicines from Animal Cell Culture** Glyn N. Stacey,John Davis,2007-06-29 Medicines from Animal Cell Culture focuses on the use of animal cell culture which has been used to produce human and veterinary vaccines interferon monoclonal antibodies and genetically engineered products such as tPA and erythropoietin It also addresses the recent dramatic expansion in cell based therapies including the use of live cells for tissue regeneration and the culture of stem cells Medicines from Animal Cell Culture Provides comprehensive descriptions of methods for cell culture and nutrition as well as the technologies for the preservation and characterisation of both the cells and the derived products Describes the preparation of stem cells and others for use in cell based therapies an area of burgeoning research Includes experimental examples to indicate expected results Covers regulatory issues from the UK the EU and the USA and reviews how these are developing around the world Addresses the key issues of standardisation and validation with chapters on GLP and GMP for cell culture processes Delivering insight into the exciting world of biological medicines and directions for further investigation into specific topics Medicines from Animal Cell Culture is an essential resource for researchers and technicians at all levels using cell culture within the pharmaceutical biotechnology and biomedical industries It is of value to laboratory managers in these industries and to all those interested in this topic alike **Commerce Business Daily** ,1998-03 Computerworld ,2002-03-25 For more than 40 years Computerworld has been the leading source of technology news and information for IT influencers worldwide Computerworld s award winning Web site Computerworld com twice monthly publication focused conference series and custom research form the hub of the world s largest global IT media network **Computerworld** ,2003-02-10 For more than 40 years Computerworld has been the leading source of technology news and information for IT influencers worldwide Computerworld s award winning Web site Computerworld com twice monthly publication focused conference series and custom research form the hub of the world s largest global IT media network *American Laboratory* ,2005

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