

# SAP – Validation and GMP Compliance

- Specific focus on SAP S/4HANA
- Validation Approach for Cloud and On-Prem
- Hands-On experiences from SAP customers
- Live demonstration: SAP Solution Manager 7.2 as a Validation platform

## SPEAKERS:



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12/13 November 2019, Berlin, Germany

## LEARNING OBJECTIVES:

- SAP S/4 HANA in a GxP environment
- Validation
  - Best practice approach
  - Process oriented vs. transaction oriented
  - Agile vs. V-Model
  - Cloud vs. On-Prem
- Operation
  - Change management
  - Lifecycle management
- Audit trail in SAP S/4HANA
- Data Integrity and SAP S/4HANA
- Insights from the Pharma Validation Group (PVG)

# Sap Validation And Gmp Compliance

**Guy Wingate**



## **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 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

**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

**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 New Scientist ,2000 **American Laboratory** ,2004 The Chemical Engineer ,1998 **Validation**

**Standard Operating Procedures** Syed Imtiaz Haider,2001-12-27 One of the most common reasons so many new drug medical device or equipment applications are rejected each year by the FDA is the failure to properly develop and document plans and procedures This is required of both U S and foreign companies wishing to market their products in the United States The lack of well defined validation standard operating procedures may result in adverse FDA findings recalls and heavy financial losses Key FDA guidelines on good manufacturing practice GMP good laboratory practice GLP and validation do not describe exactly how to develop a master validation plan how to achieve compliance or the standard operating procedures and documentation required This text provides the required validation standard operating procedures and documentation necessary for achieving compliance in the pharmaceutical industry The text and CD are designed to minimize workload and optimize time money and resources A comprehensive when and how to do it guide Validation Standard Operating Procedures provides the needed administrative solutions and guidance for achieving compliance with FDA requirements and for obtaining authorization to market products in the United States The CD ROM contains 74 template validation standard operating procedures that can be tailored to meet the regulatory compliance requirements of any pharmaceutical diagnostic medical device medical equipment and biotech product You can edit print and customize these procedures to fit your needs The book and CD work together to minimize the number of documents used and to ensure their accuracy All critical elements and requirements of validation are covered so you can easily implement them and avoid the stress that usually accompanies an FDA audit Features Provides all the information that managers need to establish functions acceptance criteria and validation procedures in compliance with FDA guidelines Includes step by step directions for translating GMP requirements into action based on your company s Master Validation Plan and execution protocols Describes how to establish test functions and prevent defects in order to produce products that are fit for use Serves as an ideal companion to Haider s Pharmaceutical Master Validation Plan **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      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

Pharmaceutical Master Validation Plan Syed Imtiaz Haider,2001-12-27 The Master Validation Plan provides a roadmap to management for on time start up of facility operations and validation of existing facilities in compliance with GMP requirements The lack of a comprehensive Master Validation Plan and well documented validation procedures is the main reason that new drug medical device medical equipment and related product applications are rejected by the FDA In fact only about 2% of the applications submitted by foreign pharmaceutical companies are approved each year This thorough guide provides the needed solutions and guidance for both foreign and U S companies to achieve FDA compliance and authorization to market their products in the United States Pharmaceutical Master Validation Plan The Ultimate Guide to FDA GMP and GLP Compliance will allow you to more easily achieve satisfactory inspections new medical product approval minimize non conformance reduce rework and rejected lots and avoid recall lots by developing and managing a Master Validation Plan The accompanying CD allows users to input the template plan into their computers and tailor it to incorporate additional regulatory requirements specific to individual companies worldwide and print the required documents Together the book and CD contain everything required to develop and execute a successful Master Validation Plan based on

FDA guidelines for the pharmaceutical industry and allows the templates to be extended to diagnostic products medical device medical equipment and biotech industry products *Validation Compliance Annual* International Validation Forum,1995-02-17 Offers an overview of validation and the current regulatory climate and provides a compendium of the regulations guidance documents issues compliance tools terminology and literature involved in computer systems validation Thoroughly examines regulations issued by the U S Food and Drug Administration the U S Environmental Protection Agency and the European Union Furnishes case studies of real world situations 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 **GMP Compliance at Validation, Qualification & Documentation with Practical Case Studies and Templates** Parviz Bayegi,2023-02-07 This book offers understandable introductions to the GMP technical basics and concepts for validation qualification of projects in the areas of Pharma Biotech ATMP Medical Device The necessary specialist knowledge about GMP guidelines validation qualification documentation was made easily and understandably accessible via example and simulated projects Topics in this book are What is qualification and what is validation Why am I qualifying How do I start with a GMP concept project What are my GMP qualification strategies How do I write a project risk analysis What is change control CC and do I need a master or sub CC How do I write a Validation Master Plan VMP What is an FMEA and why do I need an FMEA How do I write an FMEA How do I write a qualification plan QP What are FAT SAT And do I need these tests How do I create qualification documents DQ IQ OQ PQ Step by step validation and qualification using case studies **Practical Guide to SAP GTS Part 1: SPL Screening and Compliance Management** Rajen Iyer,Kevin Riddell, SAP Global Trade Services GTS helps companies maximize supply chain performance and reduces the overall cost and risk of global trade by ensuring regulatory compliance accelerating trade activity and enabling trade compliance automation The Practical Guide to SAP GTS helps the user navigate the system while offering compliance insight to maximize their return on investment Dive into difficult to navigate menus and review available functionality Using screenshots and detailed instructions readers will obtain best practices for meeting and exceeding compliance standards Includes suggested audit plans to sustain long term compliance The book is current to version 10 1 and explores version 11 0 and its new features This book offers Tips and tricks for leveraging SAP GTS to automate trade compliance Walk step by step through business processes Overview of regulatory requirements and compliance suggestions Review of Version 11 0 with screenshots Validation of Computerized Analytical Systems Ludwig Huber,2023-04-28 Validation of Computerized Analytical and Networked Systems provides the definitive rationales logic and methodology for validation of computerized analytical systems Whether you are involved with formulation or analytical development

laboratories chemical or microbiological quality control laboratories LIMS installations or any aspect of robotic in a healthcare laboratory this book furnishes complete validation details International and FDA regulations and requirements are discussed and juxtaposed with numerous practical examples that show you how to cost effectively and efficiently accomplish validation acceptable to FDA GCP GLP GMP NAMAS and EN45001 standards The templates included provide documentation examples and the many checklists found throughout the book assure that all aspects of covered in a logical sequence The chapters describe and explain such topics as the Product Life Cycle revalidation change control documentation requirements qualifications testing data validation and traceability inspection SOPs and many other that help streamline the validation process

**Validation for Medical Device and Diagnostic Manufacturers** Carol V. Desain, Charmaine V. Sutton, 1997-09-30 Implementation of FDA s Design Control requirements 21 CFR 820.30 changed an entire industry Quality System Requirements defined the approach to medical device validation Product design manufacturing process and test method validation studies must be performed before or as a product is transferred to commercial production Validation studies

Practical Guide to SAP Gts Part 1 Rajen Iyer, 2015-10-18 SAP Global Trade Services GTS helps companies maximize supply chain performance and reduces the overall cost and risk of global trade by ensuring regulatory compliance accelerating trade activity and enabling trade compliance automation The Practical Guide to SAP GTS helps the user navigate the system while offering compliance insight to maximize their return on investment Dive into difficult to navigate menus and review available functionality Using screenshots and detailed instructions readers will obtain best practices for meeting and exceeding compliance standards Includes suggested audit plans to sustain long term compliance The book is current to version 10.1 and explores version 11.0 and its new features This book offers Tips and tricks for leveraging SAP GTS to automate trade compliance Walk step by step through business processes Overview of regulatory requirements and compliance suggestions Review of Version 11.0 with screenshots

**Quality Assurance (Theory)** Mr. Rohit Manglik, 2024-09-24 Teaches quality control documentation regulatory guidelines validation processes and GMP compliance for pharmaceutical manufacturing

**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

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