Sap Validation And Gmp Compliance

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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

The global economy is climbing out from the depths to which it had plummeted during the Great Lockdown in April. But with the COVID-19 pandemic continuing to spread, many countries have slowed reopening and some are reinstating partial lockdowns to protect susceptible populations. While recovery in China has been faster than expected, the global economy's long ascent back to pre-pandemic levels of activity remains prone to setbacks.

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.

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.

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 contract organizations across the globe, the contributing authors bring readers a combined 450+ years of hands-on experience. They offer thought-provoking questions to help readers diagnose their company's challenges, needs, and available options, all with the single purpose of achieving their ultimate goals: quality, high productivity, and profitability. Auditing and GRC Automation in SAPSpringer Science & Business Media

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.

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.

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.

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