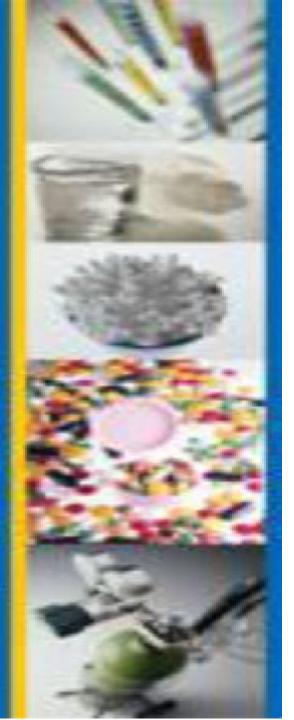
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Svetlana Yakovleva

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biosimilar products is complicated and involves numerous considerations and steps The assessment of biosimilarity and interchangeability is also complicated and difficult Biosimilar Drug Product Development presents current issues for the development of biosimilars and gives detailed reviews of its various stages and contributing factors as well as relevant regulatory pathways and pre and post approval issues **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 Pharmaceutical Dosage Forms Sandeep Nema, John D. Ludwig, 2010-08-26 Pharmaceutical Dosage Forms Parenteral Medications explores the administration of medications through other than the enteral route First published in 1984 as two volumes and then last revised in 1993 this three volume set presents the plethora of changes in the science and considerable advances in the technology associated with these products Governing Cross-Border Data Flows Svetlana Yakovleva, 2024-02-27 Governing Cross Border Data Flows explores how the European Union can simultaneously reconcile and pursue two important legal and policy objectives namely protecting fundamental rights guaranteed under the EU Charter of Fundamental Rights EU Charter concerning privacy and personal data while also maintaining and developing a binding rules based global trading system to ensure appropriate access to foreign digital markets for EU businesses The book demonstrates a significant conflict between international trade law and European data privacy law when it comes to the governance of cross border flows of personal data To resolve the tensions caused by this clash the book proposes concrete and detailed ways to ameliorate the situation from both ends international trade and personal data protection specifically through reforms of both international trade and chapter V of the General Data Protection Regulation GDPR To explain how such reforms could be effectuated Yakovleva examines the role of discourse in the evolution of trade law in the last two decades The book also paves the way for the further research necessary to design a fully fledged reform proposal of the EU framework for the transfer of personal data outside the European Economic Area Cohesion and Growth Willem Molle, 2015-05-15 To combat economic disparity and low growth the European Union has established an integrated policy system that pursues increased cohesion and smart sustainable and inclusive growth This integrated approach is realized through thousands of development projects and takes up more than a third of the total budget of the European Union Despite its significance the policy is subject to many misunderstandings and there is a lot of controversy surrounding its effectiveness Cohesion and Growth seeks to bring clarity to these issues It

presents both the theoretical and practical aspects of EU intervention a critical contribution to the understanding of the anatomy of the problems and the way to apply effective solutions to them and a systematic view of the issues at each of the subsequent stages of the whole policy cycle Offering an authoritative analysis of the problems and debates involved this book is essential reading for students policy makers project promoters and researchers concerned with this key area of European Transnational Securities Regulation Antonio Marcacci, 2022-11-25 The book provides an analysis of the emergence evolution and transformation of transnational securities regulation and of the influences from and the interactions between global regulatory powers in the field Combining insights from law and political science the work employs a two tier complementary on the books and in action approach The more classical on the books approach draws on scholarship in United States and European Union securities regulation transnational regulation and global administrative law regime complexity global governance studies and the regulatory production of the International Organisation of Securities Commissions IOSCO The law in action approach leverages the author's experience as Compliance senior professional in a multinational financial institution as well as research interviews with senior IOSCO staff The author's findings enable the reader to develop an original understanding of IOSCO its standards and its unique place in the transnational regulatory arena They also challenge the doxa that the US are the only driving regulatory power in the securities area when in fact other regulatory powers are emerging for the time being the EU The balance has shifted and regulatory compromises are achieved at different points in the rule making process

The European Union and the United States Jost Morgenstern-Pomorski, Terrence Guay, Michael Smith, 2024-11-14 In this thoroughly revised edition of The European Union and the United States authors Smith Guay and Morgenstern Pomorski delve deep into the complexities of the EU US relationship amidst pivotal shifts on the global stage By examining the relationship through the lens of competition convergence and crises this textbook goes beyond narrow focuses on the EU US relationship offering a nuanced analysis of changing dynamics It stands as the definitive and all encompassing guide to transatlantic relations considering recent developments in business trade political economy and foreign policy while carefully navigating the commonalities and differences that exist between the EU and the US This updated edition also reflects on contemporary changes such as cyber security climate change the rise of populism and the emergence of global powerhouses like China India and Brazil successfully situating the EU US relationship within a broader international context Throughout the authors diverse academic backgrounds enable an interdisciplinary approach to the material rebalancing content to include international relations comparative politics and management In doing so this textbook provides a holistic view of transatlantic affairs With additional features including focused case studies summary tables and speech extracts this text serves as the ideal companion for higher level undergraduate students and postgraduate students studying EU politics or anyone seeking to deepen their knowledge of the broader subject area

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