

Cost-Contained Regulatory Compliance

for the Pharmaceutical, Biologics,
and Medical Device Industries



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Cost Contained Regulatory Compliance For The Pharmaceutical Biologics And Medical Device Industries

Roland Wernecke, Jan Wernecke



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Cost-Contained Regulatory Compliance Sandy Weinberg,2011-04-18 This book guides the reader through FDA regulation guidelines and outlines a comprehensive strategy for cost reduction in regulatory affairs and compliance This book explains six strategies to cost effectively comply with FDA regulations while maintaining product safety and improving public access through cost controls It provides useful and practical guidance through industry case studies from pharmaceutical biotech and medical device industries

Industrial Moisture and Humidity Measurement Roland Wernecke,Jan Wernecke,2013-12-18 Moisture analysis covers a variety of methods for measuring high levels of moisture as well as trace amounts in solids liquids or gases There are many applications where trace moisture measurements are indispensable for manufacturing and for process quality assurance Trace moisture in solids must be controlled for plastics pharmaceuticals and heat treatment processes Measurement applications in gases and liquids include for example drying processes hydrocarbon processing pure gases in the semiconductor industry natural gas pipeline transport the conditioning of food and other products Written by experts with over 20 years of experience in the field this one stop guide covers all aspects of these measurements including both the theory and a wealth of practical know how As such it includes guidelines on installation on the realization of standards for absolute and relative humidity verification and traceability measurements equipment calibration methods and the latest research developments Backed by numerous case studies this practical book serves the needs of those working in the industry tasked with performing or developing new techniques and processes for moisture and humidity measurement As a result the scientist or engineer has all the information required for accurate reliable economically viable and efficient moisture measurement

Compliance Handbook for Pharmaceuticals, Medical Devices, and Biologics Carmen Medina,2003-12-09 This text lists the necessary steps for meeting compliance requirements during the drug development process It presents comprehensive approaches for validating analytical methods for pharmaceutical applications

Regenerative Medicine Technology Sean V. Murphy,Anthony Atala,2016-11-30 Miniaturization in the fields of chemistry and molecular biology has resulted in the lab on a chip Such systems are micro fabricated devices capable of handling extremely small fluid volumes facilitating the scaling of single or multiple lab processes down to a microchip sized format The convergence of lab on a chip technology with the field of cell biology facilitated the development of organ on a chip systems Such systems simulate the function of tissues and organs having the potential to bypass some cell and animal testing methods These technologies have generated high interest as applications for disease modeling and drug discovery This book edited by Drs Sean Murphy and Anthony Atala provides a comprehensive coverage of the technologies that have been used to develop organ on a chip systems Known leaders cover the basics to the most relevant and novel topics in the field including micro fabrication 3D bio printing 3D cell culture techniques biosensor design and microelectronics micro fluidics data collection and predictive analysis The book describes specific tissue types

amenable for disease modeling and drug discovery applications Lung liver heart skin and kidney on a chip technologies are included as well as a progress report on designing an entire body on a chip system Additionally the book covers applications of various systems for modeling tissue specific cancers metastasis and tumor microenvironments and provides an overview of current and potential applications of these systems to disease modeling toxicity testing and individualized medicine

Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems Loyd V. Allen, Nicholas G. Popovich, Howard C. Ansel, 2011 Thanks to its comprehensive coverage clear explanations and logical organization Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems has been a core pharmaceuticals text in the pharmacy curriculum for more than 40 years As you progress through this thoroughly updated Ninth Edition you will master all the principles practices and technologies essential for the preparation of pharmaceutical dosage forms and drug delivery systems The text's integrated approach will help you understand the interrelationships among pharmaceutical and biopharmaceutical principles product design formulation manufacturing compounding and the clinical application of dosage forms for effective patient care Book Jacket

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