Gamp 5

This textbook is a comprehensive overview of the development of cell-based biopharmaceuticals. Beginning with the underlying biology of stem cell and cell-based products, it traces the long and complex journey from preclinical concept to initiation of a pivotal clinical trial and the potential business model behind it.The book also takes into consideration the different regulatory landscapes and their continuous evolution in Europe, North America and other parts of the world. The authors describe a path to manufacture a clinical grade therapeutic that passes all necessary quality measures as a robust and marketable product including an outlook on next generation products and innovative strategies.This reference book is a must-have guide for any professional already active in biopharmaceuticals and anyone interested in getting involved in a scientific, medical or business capacity.

GAMP 5A Risk-based Approach to Compliant GxP Computerized SystemsIspe HeadquartersComputer System Validation and GAMP 5Learn Fast and Easy Quality Assurance, Risk Management and Regulatory ComplianceIndependently Published

From Yolanda Gampp, host of the massively popular, award-winning YouTube sensation "How to Cake It," comes an inspiring "cakebook" with irresistible new recipes and visual instructions for creating spectacular novelty cakes for all skill levels. On her entertaining YouTube Channel, "How to Cake It," Yolanda Gampp creates mind-blowing cakes in every shape imaginable. From a watermelon to a human heart to food-shaped cakes such as burgers and pizzas—Yolanda's creations are fun and realistic. Now, Yolanda brings her friendly, offbeat charm and caking expertise to this colorful cakebook filled with imaginative cakes to make at home. How to Cake It: A Cakebook includes directions for making twenty-one jaw-dropping cakes that are gorgeous and delicious, including a few fan favorites with a fresh twist, and mind-blowing new creations. Yolanda shares her coveted recipes and pro tips, taking you step-by-step from easy, kid-friendly cakes (no carving necessary and simple fondant work) to more difficult designs (minimal carving and fondant detail) to aspirational cakes (carving, painting and gum-paste work). Whatever the celebration, Yolanda has the perfect creation, including her never before seen Candy Apple Cake, Party Hat, Rainbow Grilled Cheese Cake, Toy Bulldozer Cake and even a Golden Pyramid Cake, which features a secret treasure chamber! Written in her inspiring, encouraging voice and filled with clear, easy-to-follow instructions and vibrant photos, How to Cake It: A Cakebook will turn beginners into confident cake creators, and confident bakers into caking superstars!

Consolidates the information LC-MS bioanalytical scientistsneed to analyze small molecules and macromolecules The field of bioanalysis has advanced rapidly, propelled by newapproaches for developing bioanalytical methods, new liquidchromatographic (LC) techniques, and new mass spectrometric (MS)instruments. Moreover, there are a host of guidelines andregulations designed to ensure the quality of bioanalyticalresults. Presenting the best practices, experimental protocols, and thelatest understanding of regulations, this book offers acomprehensive review of LC-MS bioanalysis of small molecules andmacromolecules. It not only addresses the needs of bioanalyticalscientists working on routine projects, but also explores advancedand emerging technologies such as high-resolution mass spectrometryand dried blood spot microsampling. Handbook of LC-MS Bioanalysis features contributions froman international team of leading bioanalytical scientists. Theircontributions reflect a review of the latest findings, practices,and regulations as well as their own firsthand analyticallaboratory experience. The book thoroughly examines: Fundamentals of LC-MS bioanalysis in drug discovery, drugdevelopment, and therapeutic drug monitoring The current understanding of regulations governing LC-MSbioanalysis Best practices and detailed technical instructions for LC-MSbioanalysis method development, validation, and stabilityassessment of analyte(s) of interest Experimental guidelines and protocols for quantitative LC-MSbioanalysis of challenging molecules, including pro-drugs, acylglucuronides, N-oxides, reactive compounds, and photosensitive andautooxidative compounds With its focus on current bioanalytical practice, Handbook ofLC-MS Bioanalysis enables bioanalytical scientists to developand validate robust LC-MS assay methods, all in compliance withcurrent regulations and standards.

Rear Admiral Anthony Miers VC – nicknamed 'Gamp' – was one of the Royal Navy's most controversial submarine commanders of the Second World War. Hot-tempered and incautiously spoken, he was notorious for his outbursts and those on the receiving end often ended up with a black eye, close-arrest or the sack – for some it was all three. After his death in 1985, allegations were made that Miers may have been responsible for war crimes in the Aegean in July 1941. He was soon named in the national press and there was a storm of controversy. Was Miers a war criminal? Author Brian Izzard relates his colourful war career and fully examines the war crimes allegation.

INSTANT NEW YORK TIMES BESTSELLER "One of the most important books I've ever read—an indispensable guide to thinking clearly about the world." – Bill Gates "Hans Rosling tells the story of 'the secret silent miracle of human progress' as only he can. But Factfulness does much more than that. It also explains why progress is so often secret and silent and teaches readers how to see it clearly." —Melinda Gates "Factfulness by Hans Rosling, an outstanding international public health expert, is a hopeful book about the potential for human progress when we work off facts rather than our inherent biases." - Former U.S. President Barack Obama Factfulness: The stress-reducing habit of only carrying opinions for which you have strong supporting facts. When asked simple questions about global trends—what percentage of the world's population live in poverty; why the world's population is increasing; how many girls finish school—we systematically get the answers wrong. So wrong that a chimpanzee choosing answers at random will consistently outguess teachers, journalists, Nobel laureates, and investment bankers. In Factfulness, Professor of International Health and global TED phenomenon Hans Rosling, together with his two long-time collaborators, Anna and Ola, offers a radical new explanation of why this happens. They reveal the ten instincts that distort our perspective—from our tendency to divide the world into two camps (usually some version of us and them) to the way we consume media (where fear rules) to how we perceive progress (believing that most things are getting worse). Our problem is that we don't know what we don't know, and even our guesses are informed by unconscious and predictable biases. It turns out that the world, for all its imperfections, is in a much better state than we might think. That doesn't mean there aren't real concerns. But when we worry about everything all the time instead of embracing a worldview based on facts, we can lose our ability to focus on the things that threaten us most. Inspiring and revelatory, filled with lively anecdotes and moving stories, Factfulness is an urgent and essential book that will change the way you see the world and empower you to respond to the crises and opportunities of the future. --- "This book is my last battle in my life-long mission to fight devastating

ignorance...Previously I armed myself with huge data sets, eye-opening software, an energetic learning style and a Swedish bayonet for sword-swallowing. It wasn't enough. But I hope this book will be." Hans Rosling, February 2017. Chromatography is a major analytical technique that is used throughout research, development and manufacturing in the pharmaceutical, medical device and associated industries. To demonstrate fitness for purpose with the applicable regulations, the systems must be validated. Validation of Chromatography Data Systems: Meeting Business and Regulatory Requirements introduces the basics of computer validation. It looks in detail at the requirements throughout the life cycle of a CDS for any regulated laboratory, from its concept, through writing the user requirements specification to selecting the system, testing and operational release, including using electronic signatures. This logical and uniquely organised book provides the background to the regulatory requirements, interpretation of the regulations and documented evidence needed to support a claim that a system is validated. Development of the system, risk management, operation and finally system retirement and data migration are discussed. Case studies and practical examples are provided where appropriate. Validation of Chromatography Data Systems: Meeting Business and Regulatory Requirements is ideal for the chromatographer working in analytical laboratories in the regulated pharmaceutical, contract research, biotechnology and medical device industries seeking the practical guidance required for validating their chromatography data systems in order to meet regulatory requirements. It will also be welcomed by consultants or those in regulatory agencies.

Standards, technologies, and requirements for computer validation have changed dramatically in recent years, and so have the interpretation of the standards and the understanding of the processes involved. International IT Regulations and Compliance brings together current thinking on the implementation of standards and regulations in relation to IT for a wide variety of industries. The book provides professionals in pharmaceutical and semiconductor industries with an updated overview of requirements for handling IT systems according to various Quality Standards and how to ?translate? these requirements in the regulations.

When SpongeBob becomes Sandy's assistant at Bikini Bottom's first summer camp, his enthusiasm starts to annoy the other staff.

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 r

Data integrity is the hottest topic in the pharmaceutical industry. Global regulatory agencies have issued guidance, after guidance after guidance in the past few years, most of which does not offer practical advice on how to implement policies, procedures and processes to ensure integrity. These guidances state what but not how. Additionally, key stages of analysis that impact data integrity are omitted entirely. The aim of this book is to provide practical and detailed help on how to implement data integrity and data governance for regulated analytical laboratories working in or for the pharmaceutical industry. It provides clarification of the regulatory issues and trends, and gives practical methods for meeting regulatory requirements and guidance. Using a data integrity model as a basis, the principles of data integrity and data governance are expanded into practical steps for regulated laboratories to implement. The author uses case study examples to illustrate his points and provides instructions for applying the principles of data integrity and data governance to individual laboratory needs. This book is a useful reference for analytical chemists and scientists, management and senior management working in regulated laboratories requiring either an understanding about data integrity or help in implementing practical solutions. Consultants will also benefit from the practical guidance provided.

This book constitutes the refereed proceedings of the 19th International Conference on CParallel and Distributed Computing, Applications and Technologies, PDCAT 2018, held in Jeju Island, South Korea, in August 2018. The 35 revised full papers presented along with the 14 short papers and were carefully reviewed and selected from 150 submissions. The papers of this volume are organized in topical sections on wired and wireless communication systems, high dimensional data representation and processing, networks and information security, computing techniques for efficient networks design, electronic circuits for communication systems.

The 24th European Symposium on Computer Aided Process Engineering creates an international forum where scientific and industrial contributions of computer-aided techniques are presented with applications in process modeling and simulation, process synthesis and design, operation, and process optimization. The organizers have broadened the boundaries of Process Systems Engineering by inviting contributions at different scales of modeling and demonstrating vertical and horizontal integration. Contributions range from applications at the molecular level to the strategic level of the supply chain and sustainable development. They cover major classical themes, at the same time exploring a new range of applications that address the production of renewable forms of energy, environmental footprints and sustainable use of resources and water.

Brewing Materials and Processes: A Practical Approach to Beer Excellence presents a novel methodology on what goes into beer and the results of the process. From adjuncts to yeast, and from foam to chemometrics, this unique approach puts quality at its foundation, revealing how the right combination builds to a great beer. Based on years of both academic and industrial research and application, the book includes contributions from around the world with a shared focus on quality assurance and control. Each chapter addresses the measurement tools and approaches available, along with the nature and significance of the specifications applied. In its entirety, the book represents a comprehensive description on how to address quality performance in brewing operations. Understanding how the grain, hops, water, gases, worts, and other contributing elements establish the framework for quality is the core of ultimate quality achievement. The book is ideal for users in corporate R&D, researchers, students, highly-skilled small-scale brewers, and those seeking an understanding on how the parts impact the whole in beer production, providing them with an ideal companion to complement Beer: A Quality Perspective. Focuses on the practical approach to delivering beer quality, beginning with raw ingredients Includes an analytical perspective for each element, giving the reader insights into its role and impact on overall quality Provides a hands-on reference work for daily use Presents an essential volume in brewing education that addresses areas only lightly covered elsewhere

Practical approaches to ensure that analytical methods and instruments meet GMP standards and requirements Complementing

the authors' first book, Analytical Method Validation and Instrument Performance Verification, this new volume provides coverage of more advanced topics, focusing on additional and supplemental methods, instruments, and electronic systems that are used in pharmaceutical, biopharmaceutical, and clinical testing. Readers will gain new and valuable insights that enable them to avoid common pitfalls in order to seamlessly conduct analytical method validation as well as instrument operation qualification and performance verification. Part 1, Method Validation, begins with an overview of the book's risk-based approach to phase appropriate validation and instrument qualification; it then focuses on the strategies and requirements for early phase drug development, including validation of specific techniques and functions such as process analytical technology, cleaning validation, and validation of laboratory information management systems Part 2, Instrument Performance Verification, explores the underlying principles and techniques for verifying instrument performance—coverage includes analytical instruments that are increasingly important to the pharmaceutical industry, such as NIR spectrometers and particle size analyzers—and offers readers a variety of alternative approaches for the successful verification of instrument performance based on the needs of their labs At the end of each chapter, the authors examine important practical problems and share their solutions. All the methods covered in this book follow Good Analytical Practices (GAP) to ensure that reliable data are generated in compliance with current Good Manufacturing Practices (cGMP). Analysts, scientists, engineers, technologists, and technical managers should turn to this book to ensure that analytical methods and instruments are accurate and meet GMP standards and requirements.

Guiding chromatographers working in regulated industries and helping them to validate their chromatography data systems to meet data integrity, business and regulatory needs. This book is a detailed look at the life cycle and documented evidence required to ensure a system is fit for purpose throughout the lifecycle. Initially providing the regulatory, data integrity and system life cycle requirements for computerised system validation, the book then develops into a guide on planning, specifying, managing risk, configuring and testing a chromatography data system before release. This is followed by operational aspects such as training, integration and IT support and finally retirement. All areas are discussed in detail with case studies and practical examples provided as appropriate. The book has been carefully written and is right up to date including recently released FDA data integrity guidance. It provides detailed guidance on good practice and expands on the first edition making it an invaluable addition to a chromatographer's book shelf.

HereOCOs the first book written specifically to help medical device and software engineers, QA and compliance professionals, and corporate business managers better understand and implement critical verification and validation processes for medical device software.Offering you a much broader, higher-level picture than other books in this field, this book helps you think critically about software validation -- to build confidence in your softwareOCOs safety and effectiveness. The book presents validation activities for each phase of the development lifecycle and shows: why these activities are important and add value; how to undertake them; and what outputs need to be created to document the validation process.From software embedded within medical devices, to software that performs as a medical device itself, this comprehensive book explains how properly handled validation throughout the development lifecycle can help bring medical devices to completion sooner, at higher quality, in compliance with regulations."

This book bridges the gap between practitioners of supply-chain management and pharmaceutical industry experts. It aims to help both these groups understand the different worlds they live in and how to jointly contribute to meaningful improvements in supply-chains within the globally important pharmaceutical sector. Scientific and technical staff must work closely with supply-chain practitioners and other relevant parties to help secure responsive, cost effective and risk mitigated supply chains to compete on a world stage. This should not wait until a drug has been registered, but should start as early as possible in the development process and before registration or clinical trials. The author suggests that CMC (chemistry manufacturing controls) drug development must reset the line of sight – from supply of drug to the clinic and gaining a registration, to the building of a patient value stream. Capable processes and suppliers, streamlined logistics, flexible plant and equipment, shorter cycle times, effective flow of information and reduced waste. All these factors can and should be addressed at the CMC development stage.

Software engineering requires specialized knowledge of a broad spectrum of topics, including the construction of software and the platforms, applications, and environments in which the software operates as well as an understanding of the people who build and use the software. Offering an authoritative perspective, the two volumes of the Encyclopedia of Software Engineering cover the entire multidisciplinary scope of this important field. More than 200 expert contributors and reviewers from industry and academia across 21 countries provide easy-to-read entries that cover software requirements, design, construction, testing, maintenance, configuration management, quality control, and software engineering management tools and methods. Editor Phillip A. Laplante uses the most universally recognized definition of the areas of relevance to software engineering, the Software Engineering Body of Knowledge (SWEBOK®), as a template for organizing the material. Also available in an electronic format, this encyclopedia supplies software engineering students, IT professionals, researchers, managers, and scholars with unrivaled coverage of the topics that encompass this ever-changing field. Also Available Online This Taylor & Francis encyclopedia is also available through online subscription, offering a variety of extra benefits for researchers, students, and librarians, including: Citation tracking and alerts Active reference linking Saved searches and marked lists HTML and PDF format options Contact Taylor and Francis for more information or to inquire about subscription options and print/online combination packages. US: (Tel) 1.888.318.2367; (E-mail) e-reference@taylorandfrancis.com International: (Tel) +44 (0) 20 7017 6062; (E-mail) online.sales@tandf.co.uk

Medical progress is associated with innovative product developments in medical technology, e.g. for different implants and instruments. The developments are also characterized by increasing miniaturization and precision. Hence the demands on the geometric and surface characteristics of the usually complex form elements are growing. Consequently, the need for highly-accurate dimensional inspection for the verification of these characteristics is rapidly increasing. ZEISS successfully and reliably faces these challenges. Being a leading manufacturer of medical technology as well as of measurement and inspection technology, the company ZEISS has a high level of know-how in the industrial production of medical devices and products. This book presents the metrological solutions for the medical technology and explains their application. The required measuring machines and the task-based sensors are addressed to the same extent as the challenges regarding automated 100 % checks. Methods for checking the reliability of measuring results and evaluating the inspection process quality are presented and the required procedures are described in detail. The extended regulations for medical devices and products, e.g. by FDA and MDR, place high demands on the measurement technology used and on the electronic documentation of measurement results. This is addressed in detail at the end of the book; in the appendix, easy-to-use checklists for the regulations according to 21 CFR Part 11 are provided.

Chronicles the rollicking misadventures of Forrest Gump, an idiot savant college football player whose mathematical genius does not prevent his flunking out and who finds himself drafted for Vietnam.

A paddling classic back in print with new maps, photos, details, and afterword. Christine Jerome walked into the Adirondack Museum in Blue Mountain Lake, NY, and promptly fell in love with a 9-foot, 10½-pound canoe named the Sairy Gamp. More than a century before, in 1883, the Sairy Gamp had been paddled and portaged through the Adirondacks by a sixty-one-year-old writer named George Washington Sears (his pen name was Nessmuk). The more

Jerome learned about Sears, the more she wanted to follow his route, despite her lack of camping or canoeing experience. In August 1990 she embarked in a 9-foot canoe made of Kevlar and, with her husband, John, accompanying her in a slightly larger boat, set off to retrace Sears's journey. An Adirondack Passage is part social history, part natural history, part biography of Sears, and part chronicle of a voyage. Summer turns to fall while the Jeromes make their way north, through sunshine and storms, down cottage-lined lakes and lonely wild streams. Gusting winds bully their light canoes and by mid-September the days are colder and shorter; but the longer they paddle, the more attached they become to the beauty around them. Canada geese fly overhead, monarch butterflies flutter southward, and on the larger lakes, young loons gather for their first migration to the sea. Along the way the author pauses to tell us what Sears saw when he passed by, and what happened to his favorite haunts in the ensuing century. As the history of the region unfolds we meet hermits and millionaires, hunting guides and society women, hotelkeepers and dime-novel writers, and one lost dancing bear. Christine Jerome has given us a memorable wilderness experience that readers who have never lifted a paddle will find fascinating and invigorating. This new release from Breakaway Books is the third edition, revised and updated with extra photos, maps, and a new afterword. PRAISE FOR AN ADIRONDACK PASSAGE "A fine piece of work and a great delight. " —John McPhee "An enchanting record of a canoe trip." —The New Yorker "A writer of fine and watertight prose. . . . An Adirondack Passage is uncategorizable—at once history, naturalism, sociology, and a love story—but unfailingly graceful." —Boston Globe "Personal, witty, and thoughtful—one of the best introductions to the area ever produced." —Audubon "As refreshing a break from the busyness of life as I've come across in awhile." —Newsday "The writing . . . is a constant pleasure. Jerome has a style that suits her subject, quiet and gentle as a paddle in still water. She delivers her lore with wit and whimsy, with fine descriptions and without shrill preaching or righteous posturing." —Smithsonian "The closest thing to a national nonfiction best-seller that the region has seen in ages, and deservedly so." —Adirondack Life "A captivating account. . . . She takes us into a world of hermits and millionaires, of wild streams and glorious mountain scenery." —Publishers Weekly "A delightful tale. . . . An informative, readable adventure whose history and environmental lessons are taught well." —Library Journal

This extensively reworked 2nd edition of the book includes ten new chapters. It also features an updated discussion of simulation software tools, covering topics such as simulating complex and / or expensive amplifier structures with the free LTspice software by developing a broad range of additional simulation models, especially those for triodes and transformers. The book adopts the structure used in The Sound of Silence books, with the first part, Basics - Calculations and Simulations, providing deep simulation-triggered insights into the gain and noise mechanisms of differential amplifiers, BJTs, resistors, and triodes. The second part then discusses the RIAA Phono-Amp Engine II, describing all the necessary design, simulation, calculation, construction and measurement processes for this multi-functional MC amplifier. The third part, Knowledge Transfer, presents new ideas on draft designs of the linear low-noise MC input stages (also an extremely low-noise one) and a range of practical measurement tools. Additionally, it includes a chapter on MM amplifiers and their noise production, and offers some surprising solutions. The brand new and extensive chapter on all the simulation models developed and used in the book rounds-out the voyage through the jungle of compromises, allowing best-in-class balanced MC phono-amplifiers to be produced. Lastly, the book also features an extensive index, and free downloads of all Mathcad worksheets are available on Springer's Extra Materials website (extra.springer.com).

The purpose of this book is to help you understand how computerized systems are validated using the GAMP5framework. The information will be presented in a project life cycle format. This will give you a solid idea howComputerized System Validation projects are conducted. This book is suited for anyone new to Computer SystemsValidation. It is written in a simple manner and can serve as starter guide which includes many high-level sample templates and illustration.

Instrument Engineers' Handbook – Volume 3: Process Software and Digital Networks, Fourth Edition is the latest addition to an enduring collection that industrial automation (AT) professionals often refer to as the "bible." First published in 1970, the entire handbook is approximately 5,000 pages, designed as standalone volumes that cover the measurement (Volume 1), control (Volume 2), and software (Volume 3) aspects of automation. This fourth edition of the third volume provides an in-depth, state-of-the-art review of control software packages used in plant optimization, control, maintenance, and safety. Each updated volume of this renowned reference requires about ten years to prepare, so revised installments have been issued every decade, taking into account the numerous developments that occur from one publication to the next. Assessing the rapid evolution of automation and optimization in control systems used in all types of industrial plants, this book details the wired/wireless communications and software used. This includes the ever-increasing number of applications for intelligent instruments, enhanced networks, Internet use, virtual private networks, and integration of control systems with the main networks used by management, all of which operate in a linked global environment. Topics covered include: Advances in new displays, which help operators to more quickly assess and respond to plant conditions Software and networks that help monitor, control, and optimize industrial processes, to determine the efficiency, energy consumption, and profitability of operations Strategies to counteract changes in market conditions and energy and raw material costs Techniques to fortify the safety of plant operations and the security of digital communications systems This volume explores why the holistic approach to integrating process and enterprise networks is convenient and efficient, despite associated problems involving cyber and local network security, energy conservation, and other issues. It shows how firewalls must separate the business (IT) and the operation (automation technology, or AT) domains to guarantee the safe function of all industrial plants. This book illustrates how these concerns must be addressed using effective technical solutions and proper management policies and practices. Reinforcing the fact that all industrial control systems are, in general, critically interdependent, this handbook provides a wide range of software application examples from industries including: automotive, mining, renewable energy, steel,

dairy, pharmaceutical, mineral processing, oil, gas, electric power, utility, and nuclear power.

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