User Requirements Template Pharmaceutical Engineering

This book contains both the theory and practice of risk management (RM) and provides the background, tools, and application of risk in pharmaceutical and biologics manufacturing and operations. It includes case studies and specific examples of use of RM for biological and pharmaceutical product manufacture. The book also includes useful references and a bibliography for the reader who wishes to gain additional knowledge in the subject. It aids in assisting both industry and regulatory agencies to implement compliant and effective risk management approaches, and includes case studies to help with understanding.

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

This revised publication serves as a handy and current reference for professionals engaged in planning, designing, building, validating and maintaining modern cGMP pharmaceutical manufacturing facilities in the U.S. and internationally. The new edition expands on facility planning, with a focus on the ever-growing need to modify existing legacy facilities, and on current trends in pharmaceutical manufacturing which include strategies for sustainability and LEED building ratings. All chapters have been re-examined with a fresh outlook on current good design practices.

Provides coverage of specific topics and issues in healthcare, highlighting recent trends and describing the latest advances in the field.

Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the manufacture of dosage forms until the safe reception of the finished product by the patient. The entire chain comprises of several processes: auditing, materials purchase (procurement), production, storage, distribution, quality control, and quality assurance. The quality standard for pharmaceutical production is ‘current good manufacturing practice (CGMP)‘, which is applied within the frame of a pharmaceutical quality system (PQS). This implementation, however, requires a scientific approach and has to take into account several elements such as risk assessment, life cycle, patient protection, among other factors. Hence, pharmaceutical manufacturing is a complex subject in terms of regulation, given the technical and managerial requirements. This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance. The book gives details about basic quality control requirements (such as risk management, quality hazards and management systems, documentation, clean environments, personnel training) and gives guidelines on regulatory aspects. This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector.

This book is a structured approach to designing a product and its associated manufacturing process. It shows pharmaceutical engineers and scientists involved in product and process development how to utilize QbD practices and applications effectively while complying with government regulations. Material includes discussion of how to utilize design space, models, process control methodology, and cumulative process knowledge to seek improvements in manufacturing, while maintaining and enhancing product performance. Edited by three renowned researchers in the field, this invaluable resource is an essential tool for all pharmaceutical professionals.

Pharmaceutical Production Facilities: Design and Applications considers the concepts and constraints that have to be considered in the design of small, medium and large scale production plants. The layout, along with the flow of materials and personnel through facilities are considered with reference to ensuring compliance with current good manufac

"Mastering the Requirements Process: Getting Requirements Right" sets out an industry-proven process for gathering and verifying requirements, regardless of whether you work in a traditional or agile development environment. In this sweeping update of the bestselling guide, the authors show how to discover precisely what the customer wants and needs, in the most efficient manner possible.

Pharmaceutical manufacturers are constantly facing quality crises of drug products, leading to an escalating number of product recalls and rejects. Due to the involvement of multiple factors, the goal of achieving consistent product quality is always a great challenge for pharmaceutical scientists. This volume addresses this challenge by using the Quality by Design (QbD) concept, which was instituted to focus on the systematic development of drug products with predefined objectives to provide enhanced product and process understanding. This volume presents and discusses the vital precepts underlying the efficient, effective, and cost effective development of pharmaceutical drug products. It focuses on the adoption of systematic quality principles of pharmaceutical development, which is imperative in achieving continuous improvement in end-product quality and also leads to reducing cost, time, and effort, while meeting regulatory requirements. The volume covers the important new advances in the development of solid oral dosage forms, modified release oral dosage forms, parenteral dosage forms, semisolid dosage forms, transdermal drug, delivery systems, inhalational dosage forms, ocular drug delivery systems, nanopharmaceutical products, and nanoparticles for oral delivery.

Data integrity is a critical aspect to the design, implementation, and usage of any system which stores, processes, or retrieves data. The overall intent of any data integrity technique is the same: ensure data is recorded exactly as intended and, upon later retrieval, ensure the data is the same as it was when originally recorded. Any alternation to the data is then traced to the person who made the modification. The integrity of data in a patient’s electronic health record is critical to ensuring the safety of the patient. This book is relevant to production systems and quality control systems associated with the manufacture of pharmaceuticals and medical device products and updates the practical information to enable better understanding of the controls applicable to e-records. The book highlights the e-records suitability implementation and associated risk-assessed controls, and e-records handling. The book also provides updated regulatory standards from global regulatory organizations such as MHRA, Medicines and Healthcare Products Regulatory Agency (UK); FDA, Food and Drug Administration (US); National Medical Products Association (China); TGA, Therapeutic Goods Administration (Australia); SIMGP, Russia State Institute of Medicines and Good Practices; and the World Health Organization, to name a few.

Completely revised and updated to reflect the significant advances in pharmaceutical production and regulatory expectations, this third edition of Validation of Pharmaceutical Processes examines and blueprints every step of the validation process needed to remain compliant and competitive. The many chapters added to the prior compilation examine va

Essential information for architects, designers, engineers, equipment suppliers, and other professionals who are working in or entering the biopharmaceutical manufacturing field Biomanufacturing facilities that are designed and built today are radically different than in the past. The vital information and knowledge needed to design and construct these increasingly sophisticated biopharmaceutical manufacturing facilities is difficult to find in published literature—and it’s rarely taught in architecture or design schools. This is the first book for architects and designers that fills this void. Process Architecture in Biomanufacturing Facility Design provides information on design principles of biopharmaceutical manufacturing facilities that support emerging innovative processes and technologies, use state-of-the-art equipment, are energy efficient and sustainable, and meet regulatory requirements. Relying on their many years of hands-on design and operations experience, the authors emphasize concepts and practical

approaches toward design, construction, and operation of biomanufacturing facilities, including product-process-facility relationships, closed systems and single use equipment, aseptic manufacturing considerations, design of biocontainment facility and process based laboratory, and sustainability considerations, as well as an outlook on the facility of the future. Provides guidelines for meeting licensing and regulatory requirements for biomanufacturing facilities in the U.S.A and WHO—especially in emerging global markets in India, China, Latin America, and the Asia/Pacific regions Focuses on innovative design and equipment, to speed construction and time to market, increase energy efficiency, and reduce footprint, construction and operational costs, as well as the financial risks associated with construction of a new facility prior to the approval of the manufactured products by regulatory agencies Includes many diagrams that clarify the design approach Process Architecture in Biomanufacturing Facility Design is an ideal text for professionals involved in the design of facilities for manufacturing of biopharmaceuticals and vaccines, biotechnology, and life-science industry, including architects and designers of industrial facilities, construction, equipment vendors, and mechanical engineers. It is also recommended for university instructors, advanced undergraduates, and graduate students in architecture, industrial engineering, mechanical engineering, industrial design, and industrial interior design.

This handbook details methods for sustainable compliance with GxPs and 21 CFR Part 11 validation requirements regarding computerized systems in the pharmaceutical, biotechnology, and medical device industry. The handbook follows FDA guidelines and best industry practices in defining roles, responsib

Rev. ed. of: Project management for business, engineering, and technology: principles and practice. 3rd ed. c2008.

The Textbook of Pharmaceutical Medicine is a standardreference for all those working in pharmaceutical medicine and therecognised text for the UK Faculty of Pharmaceutical MedicineDiploma. This is a comprehensive volume covering the processes bywhich medicines are developed, tested and approved. Regulations fordrug development in the UK, EU, USA, Australia and Japan arediscussed, providing relevant information for drug approval in themain continents where new drugs are developed. The chapters are written by leading academics, medical directorsand lawyers, providing authoritative and in-depth information fortrainees on the Faculty course, and for physicians working in thepharmaceutical industry. As well as thorough updating of theregulatory chapters, the 6th edition includes chapters onthese vital new areas: Paediatric regulation Ethics Due diligence and the pharmaceutical physician

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.

For more than 40 years, Computerworld has been the leading source of technology news and information for IT influencers worldwide. Computerworld's award-winning Web site (Computerworld.com), twice-monthly publication, focused conference series and custom research form the hub of the world's largest global IT media network.

A guide to the development and manufacturing of pharmaceutical products written for professionals in the industry, revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry is a practical book that highlights chemistry and chemical engineering. The book’s regulatory quality strategies target the development and manufacturing of pharmaceutically active ingredients of pharmaceutical products. The expanded second edition contains revised content with many new case studies and additional example calculations that are of interest to chemical engineers. The 2nd Edition is divided into two separate books: 1) Active Pharmaceutical Ingredients (API’s) and 2) Drug Product Design, Development and Modeling. The active pharmaceutical ingredients book puts the focus on the chemistry, chemical engineering, and unit operations specific to development and manufacturing of the active ingredients of the pharmaceutical product. The drug substance operations section includes information on chemical reactions, mixing, distillations, extractions, crystallizations, filtration, drying, and wet and dry milling. In addition, the book includes many applications of process modeling and modern software tools that are geared toward batch-scale and continuous drug substance pharmaceutical operations. This updated second edition: • Contains 30new chapters or revised chapters specific to API, covering topics including: manufacturing quality by design, computational approaches, continuous manufacturing, crystallization and final form, process safety • Expanded topics of scale-up, continuous processing, applications of thermodynamics and thermodynamic modeling, filtration and drying • Presents updated and expanded example calculations • Includes contributions from noted experts in the field Written for pharmaceutical engineers, chemical engineers, undergraduate and graduate students, and professionals in the field of pharmaceutical sciences and manufacturing, the second edition of Chemical Engineering in the Pharmaceutical Industry focuses on the development and chemical engineering as well as operations specific to the design, formulation, and manufacture of drug substance and products.

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.

Sets forth the state of the science and technology in plasma protein production With contributions from an international team of eighty leading experts and pioneers in the field, Production of Plasma Proteins for Therapeutic Use presents a comprehensive overview of the current state of knowledge about the function, use, and production of blood plasma proteins. In addition to details of the operational requirements for the production of plasma derivatives, the book describes the biology, development, research, manufacture, and clinical indications of essentially all plasma proteins with established clinical use or therapeutic potential. Production of Plasma Proteins for Therapeutic Use covers the key aspects of the plasma fractionation industry in five sections: Section 1: Introduction to Plasma Fractionation initially describes the history of transfusion and then covers the emergence of plasma collection and fractionation from its earliest days to the present time, with the commercial and not-for-profit sectors developing into a multi-billion dollar industry. Section 2: Plasma Proteins for Therapeutic Use contains 24 chapters dedicated to specific plasma proteins, including coagulation factors, albumin, immunoglobulin, and a comprehensive range of other plasma-derived proteins with therapeutic indications. Each chapter discusses the physiology, biochemistry, mechanism of action, and manufacture of each plasma protein including viral safety issues and clinical uses. Section 3: Pathogen Safety of Plasma Products examines issues and procedures for enhancing viral safety and reducing the risk of transmissible spongiform encephalopathy transmission. Section 4: The Pharmaceutical Environment Applied to Plasma Fractionation details the requirements and activities associated with plasma collection, quality assurance, compliance with regulatory requirements, provision of medical affairs support, and the manufacture of plasma products. Section 5: The Market for Plasma Products and the Economics of Fractionation reviews the commercial environment and economics of the plasma fractionation industry including future trends, highlighting regions such as Asia, which have the potential to exert a major influence on the plasma fractionation industry in the twenty-first century.

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.

Validation of computer systems is the process that assures the formal assessment and report of quality and performance measures for all the life-cycle stages of software and system development, its implementation, qualification and acceptance, operation, modification, requalification, maintenance and retirement (PICS CSV PI 011-3). It is a process that demonstrates the compliance of computer systems functional and non-functional requirements, data integrity, regulated company procedures and safety requirements, industry standards, and applicable regulatory authority’s requirements. Compliance is a state of being in adherence to application-related standards or conventions or regulations in laws and similar prescriptions. This book, which is relevant to the pharmaceutical and medical devices regulated operations, provides practical information to assist in the computer validation to production systems, while highlighting and efficiently integrating worldwide regulation into the subject. A practical approach is presented to increase efficiency and to ensure that the validation of computer systems is correctly achieved.

Revised to reflect significant advances in pharmaceutical production and regulatory expectations, Handbook of Validation in Pharmaceutical Processes, Fourth Edition examines and blueprints every step of the validation process needed to remain compliant and competitive. This book blends the use of theoretical knowledge with recent technological advancements to achieve applied practical solutions. As the industry's leading source for validation of sterile pharmaceutical processes for more than 10 years, this greatly expanded work is a comprehensive analysis of all the fundamental elements of pharmaceutical and bio-pharmaceutical production processes. Handbook of Validation in Pharmaceutical Processes, Fourth Edition is essential for all global health care manufacturers and pharmaceutical industry professionals. Key Features: Provides an in-depth discussion of recent advances in sterilization Identifies obstacles that may be encountered at any stage of the validation program, and suggests the newest and most advanced solutions Explores distinctive and specific process steps, and identifies critical process control points to reach acceptable results New chapters include disposable systems, combination products, nano-technology, rapid microbial methods, contamination control in non-sterile products, liquid chemical sterilization, and medical device manufacture

Design for Excellence contains papers from a conference organised by Brunel University. This book will be useful for designers, engineers, software developers, and other technologists working in a wide variety of engineering applications. Both those working in industry and in the academic environment will want to have access to this valuble resource. CONTENTS INCLUDE: A strategic overview of UK product development Technology management – a methodology towards achieving design excellence within the pharmaceutical industry Designing safer systems – the application of human factors methods From environmental assessment results to DFE product changes – an evaluation of quantitative and qualitative methods Design determines 70 percent of cost? A review of implications for design evaluation Using correlation chains to link customer requirements and physical laws How to manage ‘3-GEN’ products and services Strain based shallow shell finite element for circular cylindrical shells Validation of manufacturing facilities in the pharmaceuticals industry The use of formal design techniques in the development of a model device Aesthetic intelligence – optimizing user-centred design Tendering for engineering contracts An investigation on specifications – component, source information areas, and contents

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
Promoting a continued and much-needed renaissance in biopharmaceutical manufacturing, this book covers the different strategies and assembles top-tier technology experts to address the challenges of antibody purification. • Updates existing topics and adds new ones that include purification of antibodies produced in novel production systems, novel separation technologies, novel antibody formats and alternative scaffolds, and strategies for ton-scale manufacturing • Presents new and updated discussions of different purification technologies, focusing on how they can address the capacity crunch in antibody purification • Emphasizes antibodies and innovative chromatography methods for processing
The book describes the current state of digital radiology. It does not merely report single experiences, but readers will benefit from the systematic recommendations given. The book describes the development of digital radiology and networking from the late eighties up to now and outlines future perspectives. It gives readers an easy, nonetheless comprehensive overview and also how-to-do guidance for their own activities when implementing a digital radiology system. The book is a synthesis of the editors own 10 years' experience in planning and working with a fully digital, large-scale radiology department and the contributions of internationally well-known experts in the field of digital radiology.
This title is a general introduction aimed at all those involved in the engineering stages required for the manufacturr of the active ingredient and its dosage forms.
The Pharmaceutical Engineering Series is a comprehensive reference for the pharmaceutical professional covering all aspects from quality, documentation and validation through manufacturing processes to facility design and management. In 'Quality', Dr Kate McCormick provides the reader with comprehensive coverage of this vital subject, including the quality life cycle, management and cost of quality, GMP, auditing and inspections. This book with the others in the series will become a unique source of reference and educational material for the readership. Case studies and examples make the book of direct practical relevance to the professional in the pharmaceutical industry Find the answers you are looking for quickly and easily with clear indexing and referencing Reference to international standards and practice mean this book will be useful wherever you are working
Inhalation aerosols continue to be the basis for successful lung therapy for several diseases, with therapeutic strategies and the range of technology significantly evolving in recent years. In response, this third edition takes a new approach to reflect the close integration of technology with its application. After briefly presenting the general considerations that apply to aerosol inhalation, the central section of the book uses the focus on disease and therapeutic agents to illustrate the application of specific technologies. The final integrated strategies section draws the major points from the applications for disease targets and drug products.
The third edition of this best-selling book continues to offer a user-friendly, step-by-step introduction to all the key processes involved in bringing a drug to the market, including the performance of pre-clinical studies, the conduct of human clinical trials, regulatory controls, and even the manufacturing processes for pharmaceutical products. Concise and easy to read, Drugs: From Discovery to Approval, Third Edition quickly introduces basic concepts, then moves on to discuss target selection and the drug discovery process for both small and large molecular drugs. The third edition incorporates the latest developments and updates in the pharmaceutical community, provides more comprehensive coverage of topics, and includes more materials and case studies suited to college and university use. Biotechnology is a dynamic field with changes across R&D, clinical trials, manufacturing and regulatory processes, and the third edition of the text provides timely updates for those in this rapidly growing field.
Structured like a textbook, the second edition of this reference covers all aspects of biopharmaceutical manufacturing, including legal and regulatory issues, production facility design, and quality assurance, with a focus on supply chain management and regulations in emerging markets and cost control. The author has longstanding industrial expertise in biopharmaceutical production and years of experience teaching at universities. As such, this practical book is ideal for use in academia as well as for internal training within companies.
A practical guide to all key the elements of pharmaceuticals and biotech manufacturing and design Engineers working in the pharmaceutical and biotech industries are routinely called upon to handle operational issues outside of their fields of expertise. Traditionally the competencies required to fulfill those tasks were achieved piecemeal, through years of self-teaching and on-the-job experience—until now. Practical Pharmaceutical Engineering provides readers with the technical information and tools needed to deal with most common engineering issues that can arise in the course of day-to-day operations of pharmaceutical/biotech research and manufacturing. Engineers working in pharma/biotech wear many hats. They are involved in the conception, design, construction, and operation of research facilities and manufacturing plants, as well as the scale-up, manufacturing, packaging, and labeling processes. They have to implement FDA regulations, validation assurance, quality control, and Good Manufacturing Practices (GMP) compliance measures, and to maintain a high level of personal and environmental safety. This book provides readers from a range of engineering specialties with a detailed blueprint and the technical knowledge needed to tackle those critical responsibilities with confidence. At minimum, after reading this book, readers will have the knowledge needed to constructively participate in contractor/user briefings. Provides pharmaceutical industry professionals with an overview of how all the parts fit together and a level of expertise that can take years of on-the-job experience to acquire Addresses topics not covered in university courses but which are crucial to working effectively in the pharma/biotech industry Fills a gap in the literature, providing important information on pharmaceutical operation issues required for meeting regulatory guidelines, plant support design, and project

engineering Covers the basics of HVAC systems, water systems, electric systems, reliability, maintainability, and quality assurance, relevant to pharmaceutical engineering
Practical Pharmaceutical Engineering is an indispensable “tool of the trade” for chemical engineers, mechanical engineers, and pharmaceutical engineers employed by pharmaceutical and biotech companies, engineering firms, and consulting firms. It also is a must-read for engineering students, pharmacy students, chemistry students, and others considering a career in pharmaceuticals.
Biomedical Engineering: Health Care Systems, Technology and Techniques is an edited volume with contributions from world experts. It provides readers with unique contributions related to current research and future healthcare systems. Practitioners and researchers focused on computer science, bioinformatics, engineering and medicine will find this book a valuable reference.
Thoroughly acquainting the reader with freeze-drying fundamentals, Freeze-Drying/Lyophilization of Pharmaceutical and Biological Products, Second Edition carves practical guidelines from the very latest theoretical research, technologies, and industrial procedures. It delineates the best execution of steps from closure preparation and regulatory control of products to equipment sterilization and process validation. With 13 new chapters providing state-of-the-art information, the book unveils innovations currently advancing the field, including LYOGUARD® packaging for bulk freeze-drying and the irradiation of pharmaceutical and biological products.
The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensus-building process. The following new guidelines were adopted and recommended for use: Procedure for development of the WHO medicines quality assurance guidelines; Guidelines on Good Manufacturing Practices (GMP) for heating, ventilation and air-conditioning systems (HVAC) illustrative part; Guidance on GMP for Validation, including the general main text, analytical procedure validation, validation of computerized systems and qualification; in the area of interchangeability of multisource medicines: the Protocol to conduct equilibrium solubility experiments for the purpose of biopharmaceutics classification systembased classification of active pharmaceutical ingredients for biowaiver; Guidelines on Import Procedures for pharmaceutical products; and the Good Practice Guidance document on implementing the collaborative procedures. All of the above are included in this report and recommended for implementation.