Products Erweka Gmbh

Covers a widespread view of Quality by Design (QbD) encompassing the many stages involved in the development of a new drug product. The book provides a broad view of Quality by Design (QbD) and shows how QbD concepts and analysis facilitate the development and manufacture of high quality products. QbD is seen as a framework for building process understanding, for implementing robust and effective manufacturing processes and provides the underpinnings for a science-based regulation of the pharmaceutical industry. Edited by the three renowned researchers in the field, Comprehensive Quality by Design for Pharmaceutical Product Development and Manufacture guides pharmaceutical engineers and scientists involved in product and process development, as well as teachers, on how to utilize QbD practices and applications effectively while complying with government regulations. The material is divided into three main sections: the first six chapters address the role of key technologies, including process modeling, process analytical technology, automated process control and statistical methodology in supporting QbD and establishing the associated design space. The second section consisting of seven chapters present a range of thoroughly developed case studies in which the tools and methodologies discussed in the first section are used to support specific drug substance and drug-product QbD related developments. The last section discussed the needs for integrated tools and reviews the status of information technology tools available for systematic data and knowledge management to support QbD and related activities. Highlights Demonstrates Quality by Design (QbD) concepts through concrete detailed industrial case studies involving of the use of best practices and assessment of regulatory implications Chapters are devoted to applications of QbD methodology in three main processing sectors—drug substance process development, oral drug product manufacture, parenteral product processing, and solid-liquid processing Reviews the spectrum of process model types and their relevance, the range of state-of-the-art real-time monitoring tools and chemometrics, and alternative automatic process control strategies and methods for both batch and continuous processes The role of the design space is demonstrated through specific examples and the importance of understanding the risk management aspects of design space definition is highlighted Comprehensive Quality by Design for Pharmaceutical Product Development and Manufacture is an ideal book for practitioners, researchers, and graduate students involved in the development, research, or studying of a new drug and its associated manufacturing process.

What is the impact of information and communication technologies (ICTs) on the human condition? In order to address this question, in 2012 the European Commission organized a research project entitled The Onlife Initiative: concept reengineering for rethinking societal concerns in the digital transition. This volume collects the work of the Onlife Initiative. It explores how the development and widespread use of ICTs have a radical impact on the human condition. ICTs are not mere tools but rather social forces that are increasingly affecting our self-conception (who we are), our mutual interactions (how we socialise); our conception of reality (our metaphysics); and our interactions with reality (our agency). In each case, ICTs have a huge ethical, legal, and political significance, yet one with which we have begun to come to terms only recently. The impact exercised by ICTs is due to at least four major transformations: the blurring of the distinction between reality and virtuality; the blurring of the distinction between human, machine and nature; the reversal from information scarcity to information abundance; and the shift from the primacy of stand-alone things, properties, and binary relations, to the primacy of interactions, processes and networks. Such transformations are testing the foundations of our conceptual frameworks. Our current conceptual toolbox is no longer fitted to address new ICT-related challenges. This is not only a problem in itself. It is also a risk, because the lack of a clear understanding of our present time may easily lead to negative projections about the future. The goal of The Manifesto, and of the whole book that contextualises, is therefore that of contributing to the update of our philosophy. It is a constructive goal. The book is meant to be a positive contribution to rethinking the philosophy on which policies are built in a hyperconnected world, so that we may have a better chance of understanding our ICT-related problems and solving them satisfactorily. The Manifesto launches an open debate on the impacts of ICTs on public spaces, politics and societal expectations toward policymaking in the Digital Agenda for Europe’s remit. More broadly, it helps start a reflection on the way in which a hyperconnected world calls for rethinking the referential frameworks on which policies are built.

Handbook of Pharmaceutical Wet Granulation: Theory and Practice in a Quality by Design Paradigm offers a single and comprehensive reference dedicated to all aspects of pharmaceutical wet granulation, taking a holistic approach by combining introductory principles with practical solutions. Chapters are written by international experts across industry, academic and regulatory settings, and cover a wide spectrum of relevant and contemporary wet granulation topics, techniques and processes. The books' focus on process analytical technology, quality by design principles, granulation equipment, modeling, scale-up, control and real time release makes it a timely and valuable resource for all those involved in pharmaceutical wet granulation. Discusses fundamentals of theory and current industrial practice in the field of wet granulation, including product and process design and role of material properties in wet granulation Examines the modern evolution of wet granulation through current topics such as established and novel process analytical technologies (PATs), and product development and scale-up paradigms Written for scientists working within the pharmaceutical industry, as well as academics, regulatory officials and equipment vendors who provide PAT tools and granulation equipment

This volume contains the proceedings of the Eighth International Symposium on Cyclodextrins, held in Budapest, Hungary, March 31-April 2, 1996. The 147 papers collected here are milestones in the exponentially increasing cyclodextrin literature, and represent a summary of the last two years' achievement in this field, with applications in such diverse disciplines as pharmaceuticals, food, cosmetics, textiles, plastics, and chromatography. Some highlights: lipophilicity profiles of cyclodextrins by computer molecular graphics; recent toxicological studies on cyclodextrins; Buckminsterfullerene/cyclodextrin complexes;

hydroxypropyl-beta-cyclodextrin; pharmacokinetics and toxicology; peracylated cyclodextrins as drug carriers; cyclodextrins in nasal drug delivery; textile fibre surface modification by a reactive cyclodextrin; cyclodextrin-containing fabric care products; drug targeting by cyclodextrin-dimers for photodynamic cancer therapy; cyclodextrins in ophthalmologic drugs; new cyclodextrin derivatives and their potentials. Audience: This book will be of interest to researchers whose work involves pharmaceuticals, food chemicals and flavours, food additives, chromatographic methods, and biotechnology, as well as fundamental cyclodextrin research.

A Brief Guide to CCC provides a comprehensive overview of the CCC certification. The China Compulsory Certification, also known as CCC or "3C", is the People's Republic of China's mandatory certification system for products imported into or manufactured within the country. The book describes the certification system from audits to product tests and printing options as well as certifying bodies and relevant regulations. It provides insight on how to navigate the system and adequately prepare for the certification process. A Brief Guide to CCC includes a chapter dedicated just to the automotive industry with practical suggestions and useful advice.

The 31st European Symposium on Computer Aided Process Engineering: ESCAPE-31, Volume 50 contains the papers presented at the 31st European Symposium of Computer Aided Process Engineering (ESCAPE) event held in Istanbul, Turkey. It is a valuable resource for chemical engineers, chemical process engineers, researchers in industry and academia, students and consultants in the chemical industries. Presents findings and discussions from the 31st European Symposium of Computer Aided Process Engineering (ESCAPE) event

Comprehensive Quality by Design for Pharmaceutical Product Development and ManufactureJohn Wiley & Sons

This book is a printed edition of the Special Issue "Advances in Marine Chitin and Chitosan" that was published in Marine Drugs

An up-to-date overview dealing with the occurrence and key applications of agglomeration, including unwanted adhesion and beneficial size enlargement in pharmaceutical, food and animal feed, chemical, fertilizer and agrochemical, mineral, building material and ceramic, metal, solid fuel, as well as other industries. Furthermore, the book emphasizes recent developments at the level of single particles and applications of agglomeration phenomena in nanotechnology. The author has a vast academic and industrial experience as researcher, teacher, developer, designer, vendor, and user. He is an expert and consultant in the field of agglomeration, its technologies and products. This background makes the detailed evaluation of the subject possible. Wolfgang Pietsch has held a number of leading positions in both US and German companies and is a frequent speaker at conferences and seminars. He has already written three earlier books on agglomeration. Intended for everybody working in companies that process and handle particulate solids, this book helps in understanding and controlling unwanted agglomeration as well as promoting the application, development, and improvement of methods for the beneficial use of agglomeration.

The rapidly growing number of papers and patents on Cyclodextrins and their potential or actual industrial uses raised the idea to organize a Symposium on Cyclodextrins. This Symposium - held in September 1981 in Budapest, with more than 200 participants from 17 countries - proved to be very succesfull in every respect, therefore it has been accepted unanimously to organize the IInd CD-Symposium in 1984, in Tokyo. (The Budapest-Symposium got posteriorly the "First" adjective). The IInd Symposium was held together with the III. Int. Symposium on Chlatrate Compounds and Molecular Inclusion Phenomena. The IIIrd CD-Symposium also was held as a Joint Symposium, with the IVth. Chlatrate Symposium in Lancaster, U. K. ,1986. The limited time however showed, that such a broad field - from calixarenes to zeolites - can not be managed efficiently. Therefore the International Organizing Committee voted for separation of two Symposia in the future. The IVth Int. CD-Symposium was held in the Munich, in April 1988, and the Vth Chlatrate Symposium (called already Vth Int. Symposium on Inclusion Phenomena and Molecular Recognition) was held in Alabama, Sept. 1988. In Munich 220 participants from 21 countries attended 32 verbal lectures and 54 posters. This volume contains the submitted 71 manuscripts of the IVth Cyclodextrin Symposium.

The development of paediatric medicines can be challenging since this is a different patient population with specific needs. A medicine designed for use in paediatric patients must consider the following aspects: patient population variability; the need for dose flexibility; route of administration; patient compliance; excipient tolerability. For example, the toxicity of excipients may differ in children compared to adults and children have different taste preferences. Globally, about 75% of drugs do not carry regulatory approval for use in children; worldwide, many medications prescribed for the treatment of paediatric diseases are used off-label, and less than 20% of package inserts have sufficient information for treating children. This book provides an update on both state-of-the-art methodology and operational challenges in paediatric formulation design and development. It aims at re-evaluating what is needed for more progress in the design and development of age-appropriate treatments for paediatric diseases, focusing on: formulation development; drug delivery design; efficacy, safety, and tolerability of drugs and excipients.

For the first time, an English-written book collects the most salient opinions of Judge Paulo Pinto de Albuquerque (European Court of Human Rights).

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