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**WHO Expert Committee on Specifications for Pharmaceutical Preparations** CRC Press

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

Pharmaceutical Computer Systems Validation CRC Press

Concurrent Engineering (CE) is based on the premise that different phases of a product's lifecycle should be conducted concurrently and initiated as early as possible within the Product Creation Process (PCP). It has become the substantive basic methodology in many industries, including automotive, aerospace, machinery, shipbuilding, consumer goods, process industry and environmental engineering. CE aims to increase the efficiency of the PCP and reduce errors in later phases while incorporating

considerations for full lifecycle and through-life operations. This book presents the proceedings of the 22nd ISPE Inc. (International Society for Productivity Enhancement) International Conference on Concurrent Engineering (CE2015) entitled ‘Transdisciplinary Lifecycle Analysis of Systems’, and held in Delft, the Netherlands, in July 2015. It is the second in the series ‘Advances in Transdisciplinary Engineering’. The book includes 63 peer reviewed papers and 2 keynote speeches arranged in 10 sections: keynote speeches; systems engineering; customization and variability management; production oriented design, maintenance and repair; design methods and knowledge-based engineering; multidisciplinary product management; sustainable product development; service oriented design; product lifecycle management; and trends in CE. Containing papers ranging from the theoretical and conceptual to the

highly pragmatic, this book will be of interest to all engineering professionals and practitioners; researchers, designers and educators.

Thompson V. Gordon

Springer Science & Business Media

The concept of concurrent engineering (CE) was first developed in the 1980s. Now often referred to as transdiciplinary engineering, it is based on the idea that different phases of a product life cycle should be conducted concurrently and initiated as early as possible within the Product Creation Process (PCP). The main goal of CE is to increase the efficiency and effectiveness of the PCP and reduce errors in later phases, as well as incorporating considerations – including environmental implications – for the full lifecycle of the product. It has become a substantive methodology in many industries, and has also been adopted in the development of new services and service support. This book presents the proceedings of the 25th ISPE Inc. International Conference on Transdisciplinary Engineering, held in Modena, Italy, in July 2018. This international conference attracts researchers, industry experts, students, and government representatives interested in recent transdisciplinary engineering research, advancements and applications. The book contains 120 peer-reviewed papers, selected from 259 submissions from all continents of the world,

ranging from the theoretical and conceptual to papers addressing industrial best practice, and is divided into 11 sections reflecting the themes addressed in the conference program and addressing topics as diverse as industry 4.0 and smart manufacturing; human-centered design; modeling, simulation and virtual design; and knowledge and data management among others. With an overview of the latest research results, product creation processes and related methodologies, this book will be of interest to researchers, design practitioners and educators alike.

*Quality Control Applications in the Pharmaceutical and Medical Device Manufacturing Industry*
CRC Press

Algae for Food: Cultivation, Processing and Nutritional Benefits Algae are a primitive, living photosynthetic form and they are the oldest living organism. In the marine ecosystem, algae are the primary producers that supply energy required to a diverse marine organism and especially seaweed provides a habitat for invertebrates and fishes. There have been significant advances in many areas of phycology. This book describes the advances related to food and nutrition of algae achieved during the last decades, it also identifies gaps in the present knowledge and needs for the future. The 17 chapters, grouped into 6 parts, are written by phycologists. More insight on industrial exploitation of algae and their products is supported by current studies and will help academia. The first part explains new

technologies to improve the microalgal biomass, strain improvement and different methods of seaweed cultivation. In the second part, food and nutraceutical applications of algae, food safety aspects, green nanotechnology and formulation methods for the extraction and isolation of algal functional foods are described. The third part deals with pigments and carotenoids while the fourth part exploits the isolation and application of hydrocolloids, nutritional implications of algal polysaccharides and the characterization and bioactivity of fucoidans. In the fifth part, the biomedical potential of seaweed followed by agricultural applications of algae are well described. The book is an important resource for scholars that provides knowledge on wide range of topics. Key Features Covers important fields of algae from biomass production to genetic engineering aspects of algae Useful in the field of algal biotechnology, aquaculture, marine micro and macrobiology, microbial biotechnology and bioprocess technology Focuses on the therapeutic and nutritional areas of algae

ISPE Good Practice Guide Springer Science & Business Media

This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.

Quality CRC Press

As a concept,

Concurrent Engineering (CE) initiates processes with the goal of improving product quality, production efficiency and overall customer satisfaction. Services are becoming increasingly important to the economy, with more than 60% of the GDP in Japan, the USA, Germany and Russia deriving from service-based activities. The definition of a product has evolved from the manufacturing and supplying of goods only, to providing goods with added value, to eventually promoting a complete service business solution, with support from introduction into service and from operations to decommissioning. This book presents the proceedings of the 20th ISPE International Conference on Concurrent Engineering, held in Melbourne, Australia, in September 2013. The conference had as its theme Product and Service Engineering in a Dynamic World, and the papers explore research results, new concepts and insights covering a number of topics, including service engineering, cloud computing and digital manufacturing, knowledge-based engineering and sustainability in concurrent engineering.

Dictionary of Weighing Terms Springer Nature

The proceedings

contain papers accepted for the 17th ISPE International Conference on Concurrent Engineering, which was held in Cracow, Poland, September 6-10, 2010. Concurrent Engineering (CE) has a history of over twenty years. At first, primary focus was on bringing downstream information as much upstream as possible, by introducing parallel processing of processes, in order to prevent errors at the later stage which would sometimes cause irrevocable damage and to reduce time to market. During the period of more than twenty years, numerous new concepts, methodologies and tools have been developed. During this period the background for enginee ring/manufacturing has changed extensively. Now, industry has to work with global markets. The globalization brought forth a new network of experts and companies across many different domains and fields in distributed environments. These collaborations integrated with very high level of profesionalism and specialisation, provided the basis for innovations in design and manufacturing and succeeded in creating new products on a global market.

Bioreaction

Engineering CRC Press This Dictionary of Weighing Terms is a comprehensive practical guide to the terminology of weighing for all users of weighing instruments in industry and science. It explains more than 1000 terms of weighing technology and related areas; numerous illustrations assist understanding. The Dictionary of Weighing Terms is a joint work of the German Federal Institute of Physics and Metrology (PTB) and METTLER TOLEDO, the weighing instruments manufacturer. Special thanks go to Peter Brandes, Michael Denzel, and Dr. Oliver Mack of PTB, and to Richard Davis of BIPM, who with their technical knowledge have contributed to the success of this work. The Dictionary contains terms from the following fields: fundamentals of weighing, application and use of weighing instruments, international standards, legal requirements for weighing instruments, weighing accuracy. An index facilitates rapid location of the required term. The authors welcome suggestions and corrections at www.mt.com/w eighing-terms. Braunschweig (DE) and Greifensee (CH), The Authors Summer 2009 Foreword Since its

founding in 1875, the International Bureau of Weights and Measures (BIPM) has had a unique role in mass metrology. The definition of the kilogram depends on an artefact conserved and used within our laboratories. The mass embodied in this - tefact defines the kilogram, and this information is disseminated throughout the world to promote uniformity of measurements. Although the definition of the kilogram may change in the re- tively near future, reflecting the success of new technologies and new requirements, the task of ensuring world-wide uniformity of mass measurements will remain.

Pharmaceutical Manufacturing Handbook Woodhead Publishing

A practical guide to Quality by Design for pharmaceutical product development Pharmaceutical Quality by Design: A Practical Approach outlines a new and proven approach to pharmaceutical product development which is now being rolled out across the pharmaceutical industry internationally. Written by experts in the field, the text explores the QbD approach to product development. This innovative approach is based on

the application of product and process understanding underpinned by a systematic methodology which can enable pharmaceutical companies to ensure that quality is built into the product. Familiarity with Quality by Design is essential for scientists working in the pharmaceutical industry. The authors take a practical approach and put the focus on the industrial aspects of the new QbD approach to pharmaceutical product development and manufacturing. The text covers quality risk management tools and analysis, applications of QbD to analytical methods, regulatory aspects, quality systems and knowledge management. In addition, the book explores the development and manufacture of drug substance and product, design of experiments, the role of excipients, multivariate analysis, and include several examples of applications of QbD in actual practice. This important resource: Covers the essential information about Quality by Design (QbD) that is at the heart of modern pharmaceutical development Puts the focus on the industrial aspects of the new QbD approach Includes several illustrative examples of

applications of QbD in practice Offers advanced specialist topics that can be systematically applied to industry Pharmaceutical Quality by Design offers a guide to the principles and application of Quality by Design (QbD), the holistic approach to manufacturing that offers a complete understanding of the manufacturing processes involved, in order to yield consistent and high quality products. Advances in Concurrent Engineering IOS Press Advances in medical, biomedical and health services research have reduced the level of uncertainty in clinical practice. Clinical practice guidelines (CPGs) complement this progress by establishing standards of care backed by strong scientific evidence. CPGs are statements that include recommendations intended to optimize patient care. These statements are informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options. Clinical Practice Guidelines We Can Trust examines the current state of clinical practice guidelines and how they can be improved to enhance healthcare quality and patient outcomes. Clinical practice guidelines now are ubiquitous in our healthcare system. The Guidelines International

Network (GIN) database currently lists more than 3,700 guidelines from 39 countries. Developing guidelines presents a number of challenges including lack of transparent methodological practices, difficulty reconciling conflicting guidelines, and conflicts of interest. Clinical Practice Guidelines We Can Trust explores questions surrounding the quality of CPG development processes and the establishment of standards. It proposes eight standards for developing trustworthy clinical practice guidelines emphasizing transparency; management of conflict of interest ; systematic review--guideline development intersection; establishing evidence foundations for and rating strength of guideline recommendations; articulation of recommendations; external review; and updating. Clinical Practice Guidelines We Can Trust shows how clinical practice guidelines can enhance clinician and patient decision-making by translating complex scientific research findings into recommendations for clinical practice that are relevant to the individual patient encounter, instead of implementing a one size fits all approach to patient care. This book contains information directly related to the work of the Agency for Healthcare Research and Quality (AHRQ), as well as various Congressional staff and policymakers. It

is a vital resource for medical specialty societies, disease advocacy groups, health professionals, private and international organizations that develop or use clinical practice guidelines, consumers, clinicians, and payers.

*GAMP 5* IOS Press

Adopting a practical approach, the authors provide a detailed interpretation of the existing regulations (GMP, ICH), while also discussing the appropriate calculations, parameters and tests. The book thus allows readers to validate the analysis of pharmaceutical compounds while complying with both the regulations as well as the industry demands for robustness and cost effectiveness. Following an introduction to the basic parameters and tests in pharmaceutical validation, including specificity, linearity, range, precision, accuracy, detection and quantitation limits, the text focuses on a life-cycle approach to validation and the integration of validation into the whole analytical quality assurance system. The whole is rounded off with a look at future trends. With its first-hand knowledge of the industry as well as regulating bodies, this is an invaluable reference for analytical chemists, the pharmaceutical industry, pharmaceutists, QA officers, and public authorities.

*ISPE Good Practice Guide* IOS Press

The Concurrent

Engineering (CE) approach was developed in the 1980s, based on the concept that different phases of a product life cycle should be conducted concurrently and initiated as early as possible within the Product Creation Process (PCP). CE concepts have matured and become the foundation of many new ideas, methodologies, initiatives, approaches and tools. This book contains the proceedings from the 23rd ISPE Inc. International Conference on Transdisciplinary (formerly: Concurrent) Engineering, held in Curitiba, Parana, Brazil, in October 2016. The conference, entitled 'Transdisciplinary Engineering: Crossing Boundaries', provides an important forum for international scientific exchange on Concurrent Engineering and collaborative enterprises, and attracts the participation of researchers, industry experts and students, as well as government representatives. The 108 peer reviewed papers and keynote speech included here, range from theoretical and conceptual to strongly pragmatic works, which are organized into 17 sections including: Concurrent Engineering and knowledge exchange; engineering for sustainability; multidisciplinary project management; collaborative design and engineering; optimization of engineering operations and data analytics; and multidisciplinary design optimization, among others. The book gives

an overview of the latest research, advancements and applications in the field and will be of interest to researchers, design practitioners and educators.

Guideline on General Principles of Process Validation IGI Global

Quality control in pharmaceutical products and medical devices is vital for users as failing to comply with national and international regulations can lead to accidents that could easily be avoided. For this reason, manufacturing a quality medical product will support patient safety. Microbiologists working in both the pharmaceutical and medical device industries face considerable challenges in keeping abreast of the myriad microbiological references available to them and the continuously evolving regulatory requirements. Quality Control Applications in the Pharmaceutical and Medical Device Manufacturing Industry presents the importance of quality control in pharmaceutical products and medical devices, which must have very high-quality standards to not cause problems to the health of patients. It reinforces and updates the knowledge of analytical, instrumental, and biological methods to demonstrate the correct quality control and good manufacturing practice for pharmaceutical products and medical devices. Covering topics such as pharmaceutical nano systems, machine

learning, and software validation, this book is an essential resource for managers, engineers, supervisors, pharmacists, chemists, academicians, and researchers.

Method Validation in Pharmaceutical Analysis

Springer Science & Business Media

“ Collaborative Product and Service Life Cycle Management for a Sustainable World ” gathers together papers from the 15th ISPE International Conference on Concurrent Engineering (CE2008), to stimulate the new thinking that is so crucial to our sustained productivity enhancement and quality of life. It is already evident in this new century that the desire for sustainable development is increasingly driving the market to reach for new and innovative solutions that more effectively utilize the resources we have inherited from previous generations; with the obvious responsibility to future generations. Human productivity and progress can be positively engineered and managed in harmony with the provision and needs of our natural environment. One century on from the industrial revolution, this is now the time of the sustainable revolution; requiring holistic technological, process and people integrated solutions to sustained socio-economic enhancement.

Clinical Practice Guidelines We Can Trust

Ispe Headquarters

In recent years, the field

of pharmaceutical microbiology has experienced numerous technological advances, accompanied by the publication of new and harmonized compendial methods. It is therefore imperative for those who are responsible for monitoring the microbial quality of pharmaceutical/ biopharmaceutical products to keep abreast of the latest changes. Microbial Limit and Bioburden Tests: Validation Approaches and Global Requirements guides readers through the various microbiological methods listed in the compendia with easy-to-follow diagrams and approaches to validations of such test methodologies. Includes New and Updated Material Now in its second edition, this work is the culmination of research and discussions with technical experts, as well as USP and FDA representatives on various topics of interest to the pharmaceutical microbiologist and those responsible for the microbial quality of products, materials, equipment, and manufacturing facilities. New in this edition is an entire chapter dedicated to the topic of biofilms and their impact on pharmaceutical and biopharmaceutical operations. The subject of rapid methods in microbiology has been expanded and includes a discussion on the validation of alternative microbiological methods and a case study on microbial identification in support of a product contamination

investigation. Substantially updated and revised, this book assists readers in understanding the fundamental issues associated with pharmaceutical microbiology and provides them with tools to create effective microbial contamination control and microbial testing programs for the areas under their responsibility.

*A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry* Springer Science & Business Media

The CE Conference series is organized annually by the International Society for Productivity Enhancement (ISPE) and constitutes an important forum for international scientific exchange on concurrent and collaborative enterprise engineering. These international conferences attract a significant number of researchers, industrialists and students, as well as government representatives, who are interested in the recent advances in concurrent engineering research and applications. Concurrent Engineering Approaches for Sustainable Product Development in a Multi-Disciplinary Environment: Proceedings of the 19th ISPE International Conference on Concurrent Engineering contains papers accepted, peer reviewed and presented at the annual conference held at the University of Applied Sciences in Trier, Germany, from 3rd-7th

of September 2012. This covers a wide range of cutting-edge topics including: Systems Engineering and Innovation Design for Sustainability Knowledge Engineering and Management Managing product variety Product Life-Cycle Management and Service Engineering Value Engineering

**Containment Technology** ISA

Topics covered include: design technologies and applications; FE simulation for concurrent design and manufacture; methodologies; knowledge engineering and management; CE within virtual enterprises; and CE - the future.

*Eco-efficient Masonry Bricks and Blocks* National Academies Press

A guide for engineers and designers new to the field of bio-pharmaceutical process control. For the experienced automation professional, it outlines the unique design and application issues for the bio-pharmaceutical industry. For those already familiar with this industry, it provides specific advice for automating these processes.

**Dietary Supplement Good Manufacturing Practices** CRC Press

This book covers all aspects of containment technology in depth and the latest developments in this exciting field are introduced. This book is a key publication to planning engineers, production managers

and those interested in getting a picture of the different applications of the isolator technology. References on literature, laws, norms and guidelines will support the reader to become acquainted with the containment technology.

*Pharmaceutical Quality by Design* Gulf Professional Publishing

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 consensusbuilding 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.