

## Ispe Good Weighing Engineering Practice

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Pharmaceutical Manufacturing Handbook John Wiley & Sons  
Containment Technology Springer Science & Business Media  
*The Illinois Engineer* John Wiley & Sons

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.

Containment Technology IOS Press

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

Transdisciplinary Engineering Methods for Social Innovation of Industry 4.0  
Containment Technology

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.

Collaborative Product and Service Life Cycle Management for a Sustainable World World Health Organization  
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.

A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry 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.

Pharmaceutical Manufacturing Handbook Butterworth-Heinemann

Masonry walls constitute the interface between the building ' s interior and the outdoor environment. Masonry walls are traditionally composed of fired-clay bricks (solid or perforated) or blocks (concrete or earth-based), but in the past (and even in the present) they were often associated as needing an extra special thermal and acoustical insulation layer. However, over more recent years investigations on thermal and acoustical features has led to the development of new improved bricks and blocks that no longer need these insulation layers. Traditional masonry units (fired-clay bricks, concrete or earth-based blocks) that don ' t offer improved performance in terms of thermal and acoustical insulation are a symbol of a low-technology past, that are far removed from the demands of sustainable construction. This book provides an up-to-date state-of-the-art review on the eco-efficiency of masonry units, particular emphasis is placed on the design, properties, performance, durability and LCA of these materials. Since masonry units are also an excellent way to reuse bulk industrial waste the book will be important in the context of the Revised Waste Framework Directive 2008/98/EC which states that the minimum reuse and recycling targets for construction and demolition waste (CDW) should be at least 70% by 2020. On the 9th of March 2011 the European Union approved the Regulation (EU) 305/2011, known as the Construction Products Regulation (CPR) and it will be enforced after the 1st of July 2013. The future commercialization of construction materials in Europe makes their environmental assessment mandatory meaning that more information related to the environmental performance of building materials is much needed. Provides an authoritative guide to the eco-efficiency of masonry units Examines the reuse of waste materials Covers a range of materials including, clay, cement, earth and pumice

Validation of Pharmaceutical Processes 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

Eco-efficient Masonry Bricks and Blocks CRC Press

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 ISPE Good Practice Guide IOS Press

With its coverage of Food and Drug Administration regulations, international regulations, good

manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.

Handbook of Stability Testing in Pharmaceutical Development Springer Nature

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.

Method Validation in Pharmaceutical Analysis Springer Science & Business Media

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

Microbial Limit and Bioburden Tests National Academies Press

The concept of concurrent engineering (CE) was first developed in the 1980s. Now often referred to as transdisciplinary 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.

Dietary Supplement Good Manufacturing Practices IOS Press

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.

Transdisciplinary Engineering: Crossing Boundaries CRC Press

Alongside presenting the fundamentals, this book reviews the state of the art of mathematical modeling and control of bioprocesses, while demonstrating the application in various biological systems important to industry. At the same time, the application of different types of models and control strategies are illustrated, taking into account the recent developments in reactor modeling. In addition to modeling and control, the metabolic flux analysis and the metabolic design and their application to bioprocesses are considered.

Algae for Food CRC Press

The most complete guide of its kind, this is the standard handbook for chemical and process engineers. All new material on fluid flow, long pipe, fractionators, separators and accumulators, cooling towers, gas treating, blending, troubleshooting field cases, gas solubility, and density of irregular solids. This substantial addition of material will also include conversion tables and a new appendix, "Shortcut Equipment Design Methods." This convenient volume helps solve field engineering problems with its hundreds of common sense techniques, shortcuts, and calculations. Here, in a compact, easy-to-use format, are practical tips, handy formulas, correlations, curves, charts, tables, and shortcut methods that will save engineers valuable time and effort. Hundreds of common sense techniques and calculations help users quickly and accurately solve day-to-day design, operations, and equipment problems.

Dictionary of Weighing Terms Springer Science & Business Media

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 engineering/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 professionalism and specialisation, provided the basis for innovations in design and manufacturing and succeeded in creating new products on a global market.

Concurrent Engineering Approaches for Sustainable Product Development in a Multi-Disciplinary Environment IGI Global

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.

Thompson V. Gordon Springer Science & Business Media

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](http://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 artefact 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 relatively near future, reflecting the success of new technologies and new requirements, the task of ensuring world-wide uniformity of mass measurements will remain.

ISPE Good Practice Guide CRC Press

This open access book, published under a CC BY 4.0 license in the Pubmed indexed book series Handbook of Experimental Pharmacology, provides up-to-date information on best practice to improve experimental design and quality of research in non-clinical pharmacology and biomedicine.