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Concurrent Engineering is 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). Its main goal is to increase the efficiency and effectiveness of the PCP and reduce errors in the later stages, and to incorporate considerations for the full lifecycle, through-life operations, and environmental issues of the product. It has become the substantive basic methodology in many industries, and the initial basic concepts have matured and become the foundation of many new ideas, methodologies, initiatives, approaches and tools. This book presents the proceedings of the 24th ISPE Inc. International Conference on Transdisciplinary (formerly: Concurrent) Engineering (TE 2017), held in Singapore, in July 2017. The 120 peer-reviewed papers in the book are divided into 16 sections: air transport and traffic operations and management; risk-aware supply chain intelligence; product innovation and marketing management; human factors in design; human engineering; design methods and tools; decision supporting tools and methods; concurrent engineering; knowledge-based engineering; collaborative engineering; engineering for sustainability; service design; digital manufacturing; design automation; artificial intelligence and data analytics; smart systems and the Internet of Things. The book

provides a comprehensive overview of recent advances in transdisciplinary concurrent engineering research and applications, and will be of interest to researchers, design practitioners and educators working in the field.
Concurrent Engineering in the 21st Century Gulf Professional 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.
ISPE Good Practice Guide John Wiley & Sons
Fractionators, separators and accumulators, cooling towers, gas treating, blending, troubleshooting field cases, gas solubility, and density of irregular solids * Hundreds of common sense techniques, shortcuts, and calculations.
ISPE Good Practice Guide CRC Press
As with all of pharmaceutical production, the regulatory environment for the production of therapeutics has been changing as a direct result of the US FDA-initiated Quality by Design (QbD) guidelines and corresponding activities of the International Committee for Harmonization (ICH). Given the rapid growth in the biopharmaceutical area and the complexity of the molecules, the optimum use of which are still being developed, there is a great need for flexible and proactive teams in order to satisfy the regulatory requirements during process development. Process Analytical Technologies (PAT) applied in biopharmaceutical process development and manufacturing have received significant attention in recent years as an enabler to the QbD paradigm. PAT Applied in Biopharmaceutical Process Development and Manufacturing covers technological advances in measurement sciences, data acquisition, monitoring, and

control. Technical leaders present real-life case studies in areas including measuring and monitoring raw materials, cell culture, purification, and cleaning and lyophilization processes via advanced PAT. They also explore how data are collected and analyzed using advanced analytical techniques such as multivariate data analysis, monitoring, and control in real-time. Invaluable for experienced practitioners in PAT in biopharmaceuticals, this book is an excellent reference guide for regulatory officials and a vital training aid for students who need to learn the state of the art in this interdisciplinary and exciting area.

Rules of Thumb for Chemical Engineers CRC 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.

Transdisciplinary Engineering: Crossing Boundaries CRC Press

Quality, second edition, provides comprehensive application of regulatory guidelines and quality concepts and methodologies related to pharmaceutical manufacturing. It is an excellent resource for practitioners, those pursuing pharmaceutical related certifications, and for students trying to learn more about pharmaceutical manufacturing. This book provides the background theory, applied descriptions of the guidelines and concepts, plus questions and problems at the end of the chapters that will help provide practice for the reader to apply the concepts. In this book the authors share their combined 60+ years of extensive practical experience in the industry and in process improvement combined with detailed understanding of the needs of the industry and education system. This book provides real-life examples from industry and guidelines for practical application of tools that can be referenced by operators, engineers, and management.This book is fully revised, updated, and expanded with new content in areas such as QbD, Lean, Six Sigma, basic data analysis, and CAPA tools. Fully revised, updated, and expanded new edition Features new topics such as QbD, Lean, Six Sigma, basic data analysis, and CAPA tools

Includes end-of-chapter summaries and end-of-chapter question and/or problems Provides detailed steps and examples for applying the guidelines and quality tools Written in an accessible style making the content easy to understand and apply

Pharmaceutical Quality by Design IOS 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.

ISPE Good Practice Guide IOS Press

GAMP 5 provides pragmatic and practical industry guidance to achieve compliant computerized systems fit for intended use in an efficient and effective manner. This technical document describes a flexible risk-based approach to compliant GxP regulated computerized systems, based on scalable specification and verification. It points to the future of computer systems compliance by centering on principles behind major industry developments such as PQLI; ICH Q8, Q9, Q10; and ASTM E2500. This revolutionary Guide addresses the entire lifecycle of an automated system and its applicability to a wide range of information systems, lab equipment, integrated manufacturing systems, and IT infrastructures. It contains new information on outsourcing, electronic batch recording, end user applications (such as spreadsheets and small database applications), and patch management.

ISPE Good Practice Guide IOS Press

This book highlights key ideas and factors to coach and guide professionals involved in learning about Sterile Manufacturing and operational requirements. It covers regulations and guidelines instituted by the FDA, ISPE, EMA, MHRA, and ICH, emphasizing good manufacturing practice and inspection requirements in the manufacturing of medicinal products. Additionally, this book provides the fundamentals of aseptic techniques, quality by design, risk assessment, and management in support of sterile operations applications. It creates a link to the implementation of business practices in drug manufacturing and healthcare and forms a correlation between design strategies including a step-by-step process to ensure reliability, safety, and efficacy of healthcare products for human and animal use. The book also provides a connection between drug production and regulated applications by offering a review of the basic elements of sterile processing, and how to remain viable with solid strategic planning. The book is a concise reference for professionals and learners in the field of sterile operations that

governs primarily, pharmaceutical and medical device space, but can also extend to food and cosmetics that require clean (aseptic) manufacturing applications. It also helps compounding pharmacists and GMP inspectors and auditors.

ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment Springer

This book addresses the rapidly emerging field of Knowledge Management in the pharmaceutical, medical devices and medical diagnostics industries. In particular, it explores the role that Knowledge Management can play in ensuring the delivery of safe and effective products to patients. The book also provides good practice examples of how the effective use of an organisation's knowledge assets can provide a path towards business excellence.

ISPE Good Practice Guide CRC Press

Often considered a necessary evil by the pharmaceutical industry, validation is still understood by many as unrestrained bureaucracy, paperwork, and procedures whose roots and logic are obscure and only serve to slow down progress. Thoroughly defining the philosophy, application, and processes, Facility Validation: Theory, Practice, and Tools explores the validation issues relevant to the start-up of a new or upgraded manufacturing facility. The author describes policies, guidelines, and regulations relating to GMPs in the pharmaceutical industry and explores the relationship between these GMPs and the validation process. He outlines the theory and clarifies the philosophy and key principles of validation such as life-cycle approach and qualification practices. The book includes coverage of common pitfalls and how to avoid them, the difficulties and constraints a validation team has to manage, and the dangers of not adopting and following the recommended best practices. Facility validation has, in fact, become good business. It can be a tool for enhancing reliability, cost, and quality. This book makes the case that design, engineering, commissioning, and validation activities can be integrated and streamlined to accelerate a pharmaceutical manufacturing plant start-up effort, and demonstrates how to use best practices to achieve the results you desire in your organization.

GAMP Good Practice Guide IOS 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.

PAT Applied in Biopharmaceutical Process Development And Manufacturing IOS Press

Presenting the gradual evolution of the concept of Concurrent Engineering (CE), and the technical, social methods and tools that have been developed, including the many theoretical and practical challenges that still exist, this book serves to summarize the achievements and current challenges of CE and will give readers a comprehensive picture of CE as researched and practiced in different regions of the world. Featuring in-depth analysis of complex real-life applications and experiences, this book demonstrates that Concurrent Engineering is used widely in many industries and that the same basic engineering principles can also be applied to new, emerging fields like sustainable mobility. Designed to serve as a valuable reference to industry experts, managers, students, researchers, and software developers, this book is intended to serve as both an introduction to development and as an analysis of the novel approaches and techniques of CE, as well as being a compact reference for more experienced readers.

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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.

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Transdisciplinary Engineering: A Paradigm Shift Ispe Headquarters

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