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Good engineering practice, which includes elements of project management and project controls, ensures the following: Systems are specified, designed, and installed and operate in a manner that meets operational, maintenance, safety, health, environmental, ergonomic, industry, statutory, and regulatory requirements—including GxP requirements.

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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

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.

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.

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.

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/weighing-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.

Dietary Supplement GMP is a one-stop "how-to" road map to the final dietary supplement GMP regulations recently issued by the FDA covering the manufacture, packaging, and holding of dietary supplement products. The recent regulations, outlining broad goals, intentionally avoid specifics to allow for future technological advances—leaving implementation to the discretion of each firm. Given this latitude and flexibility, this new resource is an essential source of workable and practical suggestions on ways the industry can best meet the goals. Based on broad experience with GMP compliance techniques worked out over the years in the food, drug, and medical device industries, it is a must-have guide for all DS companies, especially the many smaller firms for whom this is new territory. Dietary Supplement GMP provides: a practical guide in easy to understand language to help navigate through the requirements for systems covering process and quality control suggestions and practical recommendations on "how-to" achieve full compliance explanation of the FDA's role regarding inspection, enforcement, recall/seizure of products and prosecution Dietary Supplement Good Manufacturing Practices (GMP) covers: Personnel Plants and Grounds Equipment and Utensils Sanitation of Buildings and Equipment Quality Assurance and Laboratory Operations The Quality Control Unit Production and Process Controls

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.

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.

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.

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