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this second edition of a global bestseller has been completely redesigned and extensively rewritten to take into account the new quality by design qbd and lifecycle concepts in pharmaceutical manufacturing as in the first edition the fundamental requirements for analytical method validation are covered but the second edition describes how these are applied systematically throughout the entire analytical lifecycle qbd principles require adoption of a systematic approach to development and validation that begin with predefined objectives for analytical methods these predefined objectives are established as an analytical target profile atp the book chapters are aligned with recently introduced standards and guidelines for manufacturing processes validation and follow the three stages of the analytical lifecycle method design method performance qualification and continued method performance verification case studies and examples from the pharmaceutical industry illustrate the concepts and guidelines presented and the standards and regulations from the us fda european ema and global ich regulatory authorities are considered throughout the undisputed gold standard in the field

foundations of business analytics provides fundamental knowledge for business analytics students and professionals starting from an understanding of the basic concepts of data information knowledge and data life cycle and progressing to the management of analytics projects the analytics architecture of an enterprise and classification of analytics solutions written by a leading expert in business analytics this essential text is enriched with references to key business analysis concepts such as the importance of solving the right problem and analyzing stakeholder requirements to develop successful analytics solutions structured as a solid foundation for those new to the field of business analytics this text provides the perfect entry point for students the opportunity for professionals to upskill or for managerial professionals to gain a better understanding of the value benefits and success factors of analytics foundations of business analytics is an essential resource for a wide audience including business it and data science programs at north american colleges and universities that have courses focusing on introduction to business analytics data analytics or big data

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data integrity is the hottest topic in the pharmaceutical industry global regulatory agencies have issued guidance after guidance in the past few years most of which does not offer practical advice on how to implement policies procedures and processes to ensure integrity these guidances state what but not how additionally key stages of analysis that impact data integrity are omitted entirely the aim of this book is to provide practical and detailed help on how to implement data integrity and data governance for regulated analytical laboratories working in or for the pharmaceutical industry it provides clarification of the regulatory issues and trends and gives practical methods for meeting regulatory requirements and guidance using a data integrity model as a basis the principles of data integrity and data governance are expanded into practical steps for regulated laboratories to implement the author uses case study examples to illustrate his points and provides instructions for applying the principles of data integrity and data governance to individual laboratory needs this book is a useful reference for analytical chemists and scientists management and senior management working in regulated laboratories requiring either an understanding about data integrity or help in implementing practical solutions consultants will also benefit from the practical guidance provided

the discovery of market needs and the manufacture of a product to meet those needs are integral parts of the same process since most textbooks on new product development are written from either a marketing or an engineering perspective it is important for students to encounter these two aspects of product development together in a single text product design practical methods for the systematic development of new products covers the entire new product development process from market research through concept design

embodiment design design for manufacture and product launch systematic and practical in its approach the text offers both a structured management framework for product development and an extensive range of specific design methods chapters feature design toolkits that provide detailed guidance on systematic design methods present examples with familiar products and conclude with reviews of key concepts this major text aims to turn the often haphazard and unstructured product design process into a quality controlled streamlined and manageable procedure it is ideal for students of engineering design and technology on their path to designing new products

in order to make informed decisions there are three important elements intuition trust and analytics intuition is based on experiential learning and recent research has shown that those who rely on their gut feelings may do better than those who don t analytics however are important in a data driven environment to also inform decision making the third element trust is critical for knowledge sharing to take place these three elements intuition analytics and trust make a perfect combination for decision making this book gathers leading researchers who explore the role of these three elements in the process of decision making

provides an introduction to input output analysis for sustainability practitioners and looks into the how of measuring our impacts tracking our progress and informing the decisions for a sustainable future

this book is about systems it concentrates on the engineering of human made systems and on systems analysis in the first case emphasis is on the process of bringing systems into being beginning with the identification of a need and extending through requirements determination functional analysis and allocation design synthesis and evaluation validation operation and support and disposal in the second case focus is on the improvement of systems already in being by employing the iterative process of analysis evaluation modification and feedback most systems now in existence can be improved in their effectiveness product quality affordability and stakeholder satisfaction book jacket

updated modernized digitized and streamlined edition of this classic handbook which has been educating plant and facility professionals in every aspect of maintenance engineering for more than half a century

this volume offers an up to date treatment of dynamic general equilibrium modelling the book written by some of the most experienced researchers in the field contains a rich array of policy settings the issues considered include trends in the policy use of dynamic general equilibrium models environmental policy trade liberalization and enlargement of the european union the impact of education and tax policy on human capital accumulation tax policy and the labour market and public finances in relation to population ageing

vital information on machine intelligence and pattern recognition is provided by this publication in particular the 31 papers discuss the ways in which uncertainty modelling and analysis are becoming an integral part of system definition and modelling in many fields contributions are sourced from an international base of researchers scientists and engineers working on theoretical developments and diversified applications in engineering systems the book is divided into two main parts the first uncertainty models and measures includes chapters on theoretical studies and developments carried out on uncertainty including cognitive uncertainty and how it relates to information and intelligence information fuzzy logic expert systems and neural networks there are also chapters on modelling uncertainty in the reliability assessment of complex systems linguistic connectives the principle of maximum buoyancy uncertain evidence inductive learning convex modelling new uncertainty measures and information and uncertainty the larger second part applications to engineering systems contains application oriented studies in fields related to civil electrical energy and general engineering systems the papers cover studies on general uncertainty types in structural engineering bridges transmission structures structural reliability structural identification system life cycle analysis control construction activities decision analysis signal detection risk management product quality military command and control data bases long term projections and predictions and assessment of insurance indices the book conveys the excitement advances and promises that all these fields offer to our expanding information based technological society it also hopes to stimulate the interest of other researchers around the world who are facing the challenge of new theoretical studies and innovative technological changes

this book became a bestseller because it showed system analysts how to solve problems in the real world workplace now it has been extensively updated to address the changes created by distributing computing microbased systems reengineering and other factors affecting systems analysis today new case studies illustrations and examples reflect the latest business environments

a selection of annotated references to unclassified reports and journal articles that were introduced into the nasa scientific and technical

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as well as covering traditional valuation issues this book also seeks to address the complexities associated with measuring the value of intangible assets in a practical context provides information on key aspects of business and intellectual property valuation economic damages analysis and intercompany transfer price analysis

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