

Testing Computer Software 2nd Edition

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as the generic pharmaceutical industry continues to grow and thrive so does the need to conduct adequate efficient bioequivalence studies in recent years there have been significant changes to the statistical models for evaluating bioequivalence in addition advances in the analytical technology used to detect drug and metabolite levels have made bioequivalence testing more complex the second edition of handbook of bioequivalence testing has been completely updated to include the most current information available including new findings in drug delivery and dosage form design and revised worldwide regulatory requirements new topics include a historical perspective on generic pharmaceuticals new guidelines governing submissions related to bioequivalency studies along with therapeutic code classifications models of noninferiority biosimilarity of large molecule drugs bioequivalence of complementary and alternate medicines bioequivalence of biosimilar therapeutic proteins and monoclonal antibodies new fda guidelines for bioanalytical method validation outsourcing and monitoring of bioequivalence studies the cost of generic drugs is rising much faster than in the past partly because of the increased costs required for approval including those for bioequivalence testing there is a dire need to re examine the science behind this type of testing to reduce the burden of development costs allowing companies to develop generic drugs faster and at a lower expense the final chapter explores the future of bioequivalence testing and proposes radical changes in the process of biowaivers it suggests how the cost of demonstrating bioequivalence can be reduced through intensive analytical investigation and proposes that regulatory agencies reduce the need for bioequivalence studies in humans backed by science and updated with the latest research this book is destined to

spark continued debate on the efficacy of the current bioequivalence testing paradigm

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software engineering a methodical approach second edition provides a comprehensive but concise introduction to software engineering it adopts a methodical approach to solving software engineering problems proven over several years of teaching with outstanding results the book covers concepts principles design construction implementation and management issues of software engineering each chapter is organized systematically into brief reader friendly sections with itemization of the important points to be remembered diagrams and illustrations also sum up the salient points to enhance learning additionally the book includes the author s original methodologies that add clarity and creativity to the software engineering experience new in the second edition are chapters on software engineering projects management support systems software engineering frameworks and patterns as a significant building block for the design and construction of contemporary software systems and emerging software engineering frontiers the text starts with an introduction of software engineering and the role of the software engineer the following chapters examine in depth software analysis design development implementation and management covering object oriented methodologies and the principles of object oriented information engineering the book reinforces an object oriented approach to the early phases of the software development life cycle it covers various diagramming techniques and emphasizes object classification and object behavior the text features comprehensive treatments of project management aids that are commonly used in software engineering an overview of the software design phase including a discussion of the software design process design strategies architectural design interface design database design and design and development standards user interface design operations design design considerations including system catalog product documentation user message management design for real time software design for reuse system security and the agile effect human resource management from a software engineering perspective software economics software implementation issues that range from operating environments to the marketing of software software maintenance legacy systems and re engineering this textbook can be used as a one semester or two semester course in software engineering augmented with an appropriate case or rad tool it emphasizes a practical methodical approach to software engineering avoiding an overkill of theoretical calculations where possible the primary objective is to help students gain a solid grasp of the activities in the software development life cycle to be confident about taking on new software engineering projects

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