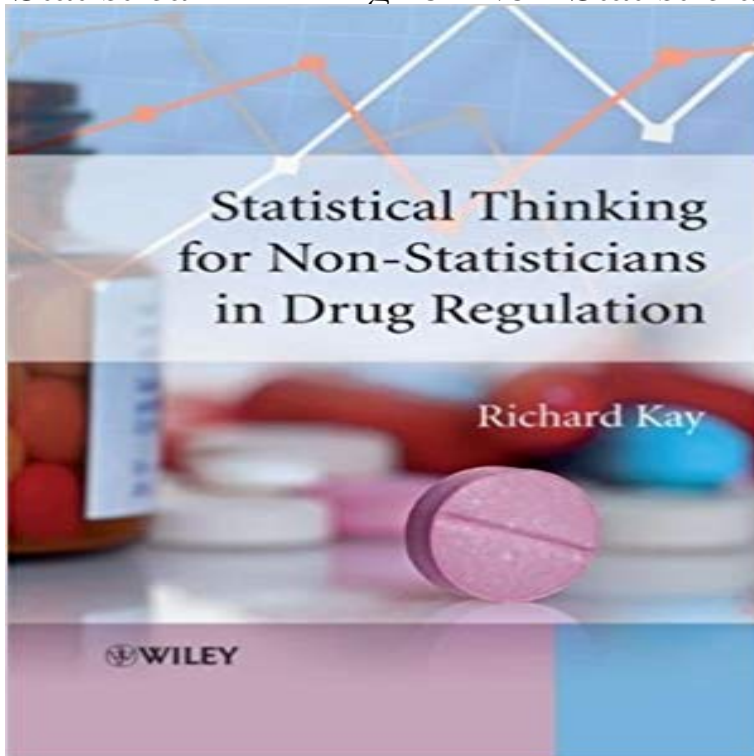


Statistical Thinking for Non-Statisticians in Drug Regulation



Written by a well-known lecturer and consultant to the pharmaceutical industry, this book focuses on the pharmaceutical non-statistician working within a very strict regulatory environment. Statistical Thinking for Clinical Trials in Drug Regulation presents the concepts and statistical thinking behind medical studies with a direct connection to the regulatory environment so that readers can be clear where the statistical methodology fits in with industry requirements. Pharmaceutical-related examples are used throughout to set the information in context. As a result, this book provides a detailed overview of the statistical aspects of the design, conduct, analysis and presentation of data from clinical trials within drug regulation. Statistical Thinking for Clinical Trials in Drug Regulation: Assists pharmaceutical personnel in communicating effectively with statisticians using statistical language Improves the ability to read and understand statistical methodology in papers and reports and to critically appraise that methodology Helps to understand the statistical aspects of the regulatory framework better quoting extensively from regulatory guidelines issued by the EMEA (European Medicines Evaluation Agency), ICH (International Committee on Harmonization) and the FDA (Food and Drug Administration)

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