Watson Lims User Guide

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practical approaches to ensure that analytical methods and instruments meet gmp standards and requirements complementing the authors first book analytical method validation and instrument performance verification this new volume provides coverage of more advanced topics focusing on additional and supplemental methods instruments and electronic systems that are used in pharmaceutical biopharmaceutical and clinical testing readers will gain new and valuable insights that enable them to avoid common pitfalls in order to seamlessly conduct analytical method validation as well as instrument operation qualification and performance verification part 1 method validation begins with an overview of the book s risk based approach to phase appropriate validation and instrument qualification it then focuses on the strategies and requirements for early phase drug development including validation of specific techniques and functions such as process analytical technology cleaning validation and validation of laboratory information management systems part 2 instrument performance verification explores the underlying principles and techniques for verifying instrument performance coverage includes analytical instruments that are increasingly important to the pharmaceutical industry such as nir spectrometers and particle size analyzers and offers readers a variety of alternative approaches for the successful verification of instrument performance based on the needs of their labs at the end of each chapter the authors examine important practical problems and share their

solutions all the methods covered in this book follow good analytical practices gap to ensure that reliable data are generated in compliance with current good manufacturing practices cgmp analysts scientists engineers technologists and technical managers should turn to this book to ensure that analytical methods and instruments are accurate and meet gmp standards and requirements

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