

Assay Development

Fundamentals and Practices



Ge Wu

 WILEY

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Nader Rifai



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purposes provides examples from different technologies which includes standard of care approved assays as well as for investigational use and for research use only assays It also includes new data for biomarkers in different therapeutic indications and offers case studies and practical examples This book serves as a reference to drug developers IVD providers clinical labs healthcare givers academicians and researchers for best practices to help increase the probability of success in drug development and improve patient management Provides the unique insight of an expert with extensive experience in diagnostics and clinical laboratory on one side and drug discovery and development on the other side Addresses the challenges of drug development and precision medicine and suggests how to eliminate or mitigate these challenges through better utilization of biomarkers and diagnostics in drug development and patient management Features case studies and real life examples from different classes of biomarkers on different platforms for different therapeutic areas and includes more than 200 illustrations

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new mass spectrometric MS instruments Moreover there are a host of guidelines and regulations designed to ensure the quality of bioanalytical results Presenting the best practices experimental protocols and the latest understanding of regulations this book offers a comprehensive review of LC MS bioanalysis of small molecules and macromolecules It not only addresses the needs of bioanalytical scientists working on routine projects but also explores advanced and emerging technologies such as high resolution mass spectrometry and dried blood spot microsampling Handbook of LC MS Bioanalysis features contributions from an international team of leading bioanalytical scientists Their contributions reflect a review of the latest findings practices and regulations as well as their own firsthand analytical laboratory experience The book thoroughly examines Fundamentals of LC MS bioanalysis in drug discovery drug development and therapeutic drug monitoring The current understanding of regulations governing LC MS bioanalysis Best practices and detailed technical instructions for LC MS bioanalysis method development validation and stability assessment of analyte s of interest Experimental guidelines and protocols for quantitative LC MS bioanalysis of challenging molecules including pro drugs acyl glucuronides N oxides reactive compounds and photosensitive and autooxidative compounds With its focus on current bioanalytical practice Handbook of LC MS Bioanalysis enables bioanalytical scientists to develop and validate robust LC MS assay methods all in compliance with current regulations and standards

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