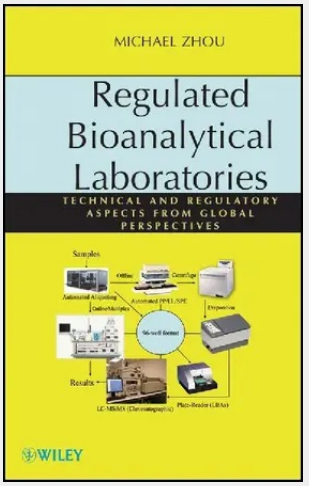
Zhou

Regulated Bioanalytical Laboratories

Technical and Regulatory Aspects from Global Perspectives



This book provides useful information for bioanalytical / analytical scientists, analysts, quality assurance managers, and all personnel in bioanalytical laboratories through all aspects of bioanalytical technical and regulatory perspectives within bioanalytical operations and processes. Readers learn how to develop and implement strategies for routine, non-routine, and standard bioanalytical methods and on the entire equipment hardware and software qualification process. The book also gives guidelines on qualification of certified standards and in-house reference material as well as on people qualification. Finally, it guides readers through stressless internal and third party laboratory audits and inspections. It takes account to most national and international regulations and quality and accreditation standards, along with corresponding interpretation and inspection guides. The author elaborates on highly comprehensive content, making it easy not only to learn the subject but also to quickly implement the recommendations.

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