Regulated Bioanalytical Laboratories: Technical and Regulatory Aspects from Global Perspectives

Michael Zhou
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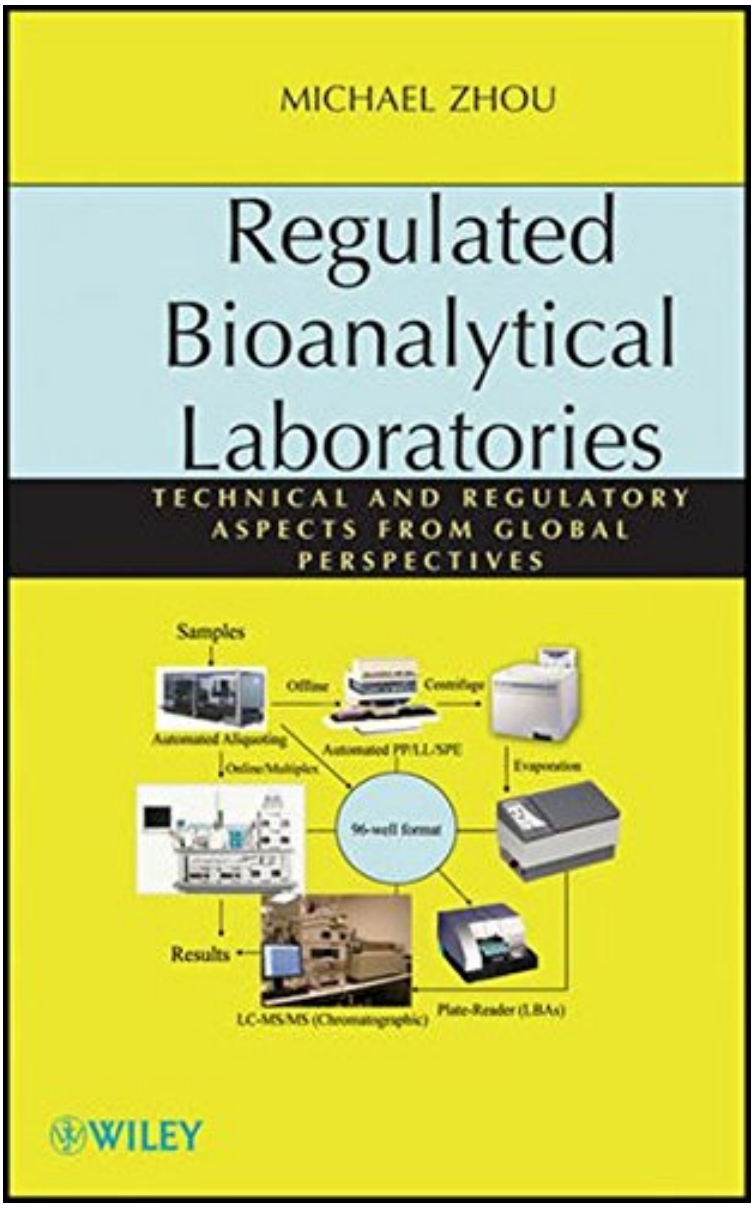

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This book provides useful information for bioanalytical / analytical scientists, analysts, quality assurance managers, and all personnel in bioanalytical laboratories through all aspects of bioanalytical technical and regulatory perspectives within 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.

From the Back CoverEverything staff members in bioanalytical/analytical laboratories and quality assurance unit need to know about technical expertise and regulatory compliance This book provides much-needed practical information on how to generate and review data for regulatory consideration in the biotech, pharmaceutical, and life science industries. It explains in detail how to develop and implement effective strategies for meeting technical challenges, Good Laboratory Practice (GLP) and GxP requirements from global perspectives, with an emphasis on tools and techniques for ensuring the quality and integrity of study data. Readers will gain invaluable insight into the entire hardware and software qualification process as well as people qualification, learn how to get through laboratory audits and inspections with ease, and acquire a thorough understanding of all regulatory issues relevant to their work. Coverage includes: International standards and regulations from the US FDA, USP, ICH, OECD, WHO, ISO, EMEA, and EU Requirements, objectives, and implementation of GLP and GxP quality systems Facility and personnel infrastructure and qualification Techniques for modern bioanalytical / analytical sample preparation and essential concepts in extraction chemistry and separation mechanisms Specific strategies for the efficient use of laboratory automation with high throughput Instrumental analysis for hyphenated techniques such as LC-MS/MS and so on Important laboratory applications of Ligand Binding Assays (LBAs) andbiomarker assays A must-have for scientists, graduate students, and quality assurance managers in bioanalytical laboratories, Regulated Bioanalytical Laboratories is also an essential reference for anyone interested in the overall technical know-how, regulatory, and quality assurance trends in the field.About the AuthorMichael Zhou, PhD, is Director of Bioanalytical Chemistry at Synta Pharmaceuticals Corporation and a highly regarded expert on analytical/bioanalytical operations, regulatory compliance, including Good Laboratory Practice (GLP), cGMP, GCP regulations, and ICH, GCLP, BMV guidelines. Dr. Zhou has given numerous presentations and workshops / short courses on the topics at national and international conferences and has authored over fifty research articles and two book chapters on analytical/bioanalytical chemistry