



Analytical Instrument Qualification

Aaps Guide On Instrument Qualification

Lingsheng Yao

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Regulated Bioanalytical Laboratories Michael Zhou,2011-02-22 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

Handbook of Analytical Validation Michael E. Swartz,Ira S. Krull,2012-04-24 Written for practitioners in both the drug and biotechnology industries this handbook carefully compiles the current regulatory requirements to correctly and properly validate a new or modified analytical method The Handbook of Analytical Validation is designed to teach readers how to fully and correctly adapt new or modified analytical methods to meet regulatory requirements The contents offer the latest regulatory requirements for submitting applications for new drugs or other applications as regards analytical method validation The chapters apply to both small molecules in the conventional pharmaceutical industry as well the biotech industry

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