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| Altri autori (Persone)  | CaroliSergio <1943-><br>ZarayGyula   |
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| Nota di contenuto       | Analytical Techniques for Clinical Chemistry: Methods and Applications;<br>CONTENTS; FOREWORD; PREFACE; CONTRIBUTORS; PART I: Exploring<br>Fundamentals; 1. Good Clinical Practice Principles: Legal Background<br>and Applicability; Summary; 1.1. Introduction; 1.2. Good Clinical<br>Practice; 1.2.1. ICH E6: Guidelines for Good Clinical Practice; 1.2.2.<br>WHO Guidelines for Good Clinical Practice for Trials on Pharmaceutical<br>Products; 1.2.3. WHO Handbook for Good Clinical Research Practice<br>Guidance for Implementation; 1.2.4. WHO Good Clinical Laboratory<br>Practice<br>1.3. Good Clinical Practice: Legal Background in the European Union1.4.<br>Good Clinical Practice: Applicability in the European Union; 1.4.1. EU<br>2007 Conference on the Implementation and Applicability in the |

European Union of Legislation on Clinical Trials of Medical Products; 1.4.2. Directives 2001/20/EC, 2005/28/EC, and Good Clinical Practice in Case of Noncommercial Clinical Trials; 1.5. Good Clinical Practice and Bioequivalence Trials: GCP Inspections and Laboratories; 1.5.1. General Aspects; 1.5.2. EMA Guidelines on Bioequivalence Studies 1.5.3. EMA Reflection Paper for Applicants Who Want to Submit Bioequivalence Performed Outside the European Union 1.5.4. Good Clinical Practice Bioequivalence Inspections; 1.5.5. Good Clinical Practice Clinical Laboratory Inspections; 1.5.6. Good Clinical Practice Inspections on Phase I Units; 1.6. Good Clinical Practice for Clinical Trials with Advanced Therapy Medicinal Product; 1.7. Good Clinical Practice and Clinical Trials in Developing Countries; 1.7.1. The Increase of Clinical Trials in Developing Countries; 1.7.2. European Union Legislation and Clinical Trials in Developing Countries

References

2. Clinical Chemistry and the Quest for Quality; Summary; 2.1. Introduction; 2.2. Quality Today; 2.2.1. General Aspects; 2.2.2. Major Quality Systems and Their Scope; 2.3. Conclusions; References;

3. Uncertainty in Clinical Chemistry Measurements Including Preanalytical Variables; Summary; 3.1. Introduction; 3.2. Analytical Uncertainty in Laboratory Results; 3.2.1. General Aspects; 3.2.2. Control Materials; 3.2.3. Estimating Analytical Precision; 3.2.4. Within-Run Precision (Repeatability); 3.2.5. Total Analytical Precision (Reproducibility) 3.2.6. Estimating Precision Using Duplicates 3.3. Trueness and Traceability; 3.3.1. Basic Concepts; 3.3.2. Reference Methods and Materials; 3.3.3. Estimating the Trueness; 3.3.4. Factorizing the Patients' Results; 3.3.5. Changing Reagent Lot; 3.3.6. Analytical Specificity; 3.3.7. Method Validation; 3.4. Proficiency Testing; 3.4.1. Background Information; 3.4.2. Choice of EQA Schemes; 3.4.3. Interpretation and Actions; 3.5. Biological Variations and Quality Goals; 3.6. Reference Intervals; 3.6.1. Establishing Reference Intervals; 3.6.2. Transferring Reference Intervals 3.7. Estimating Preanalytical Uncertainty

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## Sommario/riassunto

Discover how analytical chemistry supports the latest clinical research  
This book details the role played by analytical chemistry in fostering clinical research. Readers will discover how a broad range of analytical techniques support all phases of clinical research, from early stages to the implementation of practical applications. Moreover, the contributing authors' careful step-by-step guidance enables readers to better understand standardized techniques and steer clear of everyday problems that can arise in the lab. Analytical Techniques for Clinical Chemistry

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