OMICS Group Conferences
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Chase Bourke, J Bioequiv Availab 2014, 6:5
http://dx.doi.org/10.4172/0975-0851.S1.019

5th World Congress on
Bioavailability and Bioequivalence
Pharmaceutical R&D Summit
September 29-October 01, 2014 DoubleTree by Hilton Baltimore-BWI Airport, USA

Regulatory perspectives on bioanalytical inspections for BA/BE studies

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Adherence to FDA regulatory requirements for bioavailability and bioequivalence studies is essential for a compliant bioanalytical program. Inspections by the FDA have revealed that regulations can be misinterpreted or poorly implemented, SOPs may be lacking or not adhered to, and scientific principles not followed. FDA guidance documents provide clarity to regulations, but scientific decisions are still the responsibility of a bioanalytical firm, the quality assurance department, and the scientific staff jointly. The primary objective of FDA inspections is to ensure the quality and integrity of data submitted to the Agency. As part of this objective, inspections determine if the data submitted to support regulatory applications are reliable. Critical thinking approaches are necessary to successfully implement bioanalytical methods for BA/BE studies. Several cases will be presented to illustrate regulatory thinking from an inspection perspective.

Biography

Chase Bourke is a pharmacologist and reviewer in the Food and Drug Administration Office of Scientific Investigations, Division of Bioequivalence and Good Laboratory Practice Compliance. His 10 years of biotechnology experience includes positions at Digene, the J. Craig Venter Institute, and Quintiles. He received his PhD in Pharmacology at Emory University and his BS in Biochemistry at University of Maryland, College Park.

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