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Current global challenges in the Bioequivalence of CR/MR and Multiphasic formulations of drugs

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Modified release products are becoming more and more sophisticated in their design and release, prompting a careful scientific re-evaluation of what pharmacokinetic metrics and statistical tests are needed to make sure that generic products are truly equivalent to their reference counterparts, while ensuring that additional evaluations or tests are not required needlessly. It is therefore crucial that regulatory requirements are scientifically sound to protect the public, while allowing access to generic products once market exclusivity and patent protection have elapsed. This presentation will be broken up in three parts. A summary of the current requirements from US FDA, Health Canada and EMA will first be reviewed for the different classes of modified release products available. A critical evaluation of these requirements will follow. Case examples will be presented to highlight certain points. Finally, specific scientific recommendations will be proposed in order to stimulate further discussion and debate on this topic from a global harmonization perspective.

Biography

Murray P. Ducharme has a pharmacy degree from the University of Montreal, and a post-graduate Pharm.D. from Wayne State University. He has been with Cetero Research since 2007 where he is globally responsible for scientific and regulatory affairs. His research interests have focused on the role of modeling and simulations to better understand the clinical pharmacology of drugs and optimizing the drug development process. Dr. Ducharme has been principal or sub-investigator on thousands of trials, has authored more than 150 articles, abstracts, book chapters and manuals, and has presented internationally more than 200 posters and seminars.