



Redefining Drug Discovery

2006 FDA DRAFT GUIDANCE ENCOURAGES EARLIER TESTING

It makes sense. Given the number of compounds that fail in clinical trials, it seems logical to conduct ADME testing much earlier in the drug development process. As documented in the 2006 FDA draft guidance, drug transporters can make significant contributions to clinically relevant drug-drug interactions, and this information must be included in NDA submissions.

However, not all companies are equipped to conduct the sophisticated analysis necessary to effectively predict drug-drug interactions and make the decisions necessary about candidate advancement. Knowing the critical nature of this decision, ADMETRx has developed the tools and expertise that can successfully assist drug development companies in addressing this challenge successfully. According to ADMETRx CEO and cofounder, Phil Burton:

"One of our specialties is in permeability, particularly using MDR1-MDCK cells. The FDA directive specifically states that in vitro permeability studies in the MDCK cell model are to be conducted. This currently primarily concerns P-glycoprotein, an extensively expressed ATP-binding cassette (ABC) transporter, but this scope will likely broaden to include others from the ABC transporter family."

Thus, by conducting permeability studies earlier in the compound development cycle which would allow effective prediction of drug-drug interactions, drug development companies do not have to wait until later in the cycle to make their lead advancement decisions.

This issue was addressed by Philip Burton, PhD in a presentation he delivered to the FDA in May, 2008. In abstract form, it will be presented as a poster at the 2008 AAPS Annual Meeting in Atlanta November 16-20, 2008, and is titled, **"Strategy for Characterizing P-glycoprotein Substrate and Inhibitor Potential for Sparingly Soluble Drugs."**

To learn more about how ADMETRx can increase efficiency, reduce costs and help you meet your drug discovery goals, please respond to this email, contact Marie Warren at 1.269.353.5541 or visit www.admetrx.com.

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