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Expanding BCS-based biowaivers

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Record numbers of patent expirations, unprecedented expansion of the global generics market, and mounting pressure from government and customers for low-cost drugs, contribute to the need for reliable, economical, and expeditious test systems for supporting BCS-based biowaivers. And yet, this pathway remains underutilized by the generic industry. This session will review progress which has been made in BCS permeability classification techniques, including identification of increasingly accurate internal standards and optimized pH conditions. Current limitations will also be explored, including passive transport requirements and solubility conditions. Opportunities for applying updated science and ultimately expanding the utility of BCS biowaivers will be discussed.

Biography

Lisa Murray, Associate Director of Business Operations, joined Absorption Systems in 2008. Applying her background in drug delivery research, she provides consultative support for the pharmaceutical industry and designs in vitro and in vivo studies related to lead optimization, candidate selection, and preclinical development. She plays an integral role in the operations of the company, including business development, marketing, key account management, and regulatory/grant support. She has presented at various international conferences on the topics of drug-drug interactions, drug transporters, and BCS biowaivers. She received her MS in Biology from Saint Joseph's University, as a Research Fellow at Lankenau Institute for Medical Research, where she published several articles on transmucosal gastric leak induced by proton pump inhibitors, and transporters related to esophageal cancer.

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