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Improving outcomes: A decade of industry and regulatory experience with BCS based biowaivers

For over a decade, in vitro BCS classification has been recognized as a reliable and powerful tool to enable waivers of clinical bioequivalence studies. While elegant in simplicity of concept, the in vitro experiment can be surprisingly intricate in practice and, when used correctly, offers extended and varied applications. Absorption Systems' history with Caco-2 includes encounters with a multitude of diverse and challenging compounds, presenting unique obstacles and prompting innovative solutions to facilitate accurate classification and subsequent biowaivers.

With a fully-validated in vitro BCS offering, Absorption Systems has engaged in extensive dialogue with regulatory agencies regarding pragmatic considerations and maximizing system utility. This dynamic exchange is reflected in an increasingly sophisticated experimental approach and in a developing perspective on what can be considered as 'favorable' drug properties. During this presentation, we will discuss the evolution and execution of our BCS study design, solutions to combat test compound & test system challenges, and possible future directions.

Biography

Lisa Murray, M.S. Associate Director of Business Operations, has been with Absorption Systems since 2008. Ms. Murray's position requires extensive customer interaction as well as internal communication and coordination. In her current role, Ms. Murray oversees a team of business development and account managers, designs in vitro and in vivo studies related to lead optimization, candidate selection, and preclinical development, and continuously works toward customer satisfaction. In addition to her current role, Ms. Murray's experience extends to the lab, where she has worked with animal models, human tissue specimens, cell cultures, and permeability and drug delivery methods. She received her M.S. in Biology from Saint Joseph's University, as a research fellow at Lankenau Institute for Medical Research.

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