

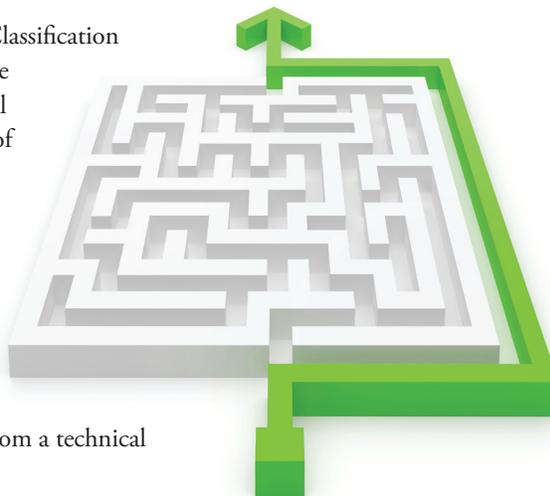
BCS-Based Biowaivers: A Regulatory Tool for Streamlined Drug Development

APANAC 2012 | Convention Center | City of Knowledge, Panamá
Friday, October 19, 2012 | 8:00 am – 11:00 am

For over a decade, *in vitro* Biopharmaceutics Classification System (BCS) 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* experiments that support the classification can be surprisingly intricate in practice and, when used correctly, offer extended and varied applications. Join us for a comprehensive overview of BCS and learn to unlock its potential for the approvals of your various drug products.

Attendees will:

- acquire a comprehensive understanding of BCS, from a technical standpoint and regulatory perspective
- be able to outline and establish experimental techniques for the determination of BCS-relevant permeability and solubility
- gain insights in overcoming experimental obstacles and maximizing accurate outcomes
- be equipped to employ BCS for significant cost and temporal economies via waiver of clinical BA/BE and DDI studies
- discover future directions and applications for BCS testing



APANAC Pre-Conference Workshop Program

8:00 Check-in

8:30 The Basis For BCS-Based Biowaivers: Scientific and Regulatory Perspectives

Ismael J. Hidalgo, Ph.D., Chief Scientific Officer will introduce the fundamental principles supporting BCS-based biowaivers, and the compelling impetus for such. The adaptation of BCS, and impact from the manufacturer, consumer and regulatory perspectives will be addressed.

9:00 Use of Permeability for BCS Classification: Comparing Non-Clinical Techniques

Hao Cheng, Ph.D., Senior Research Scientist will discuss tools and methods for BCS classification, including a comprehensive comparison of non-clinical intestinal permeation techniques.

9:30 Coffee Break

10:00 Improving Outcomes: A Decade of Experience with BCS Biowaivers

Lisa Murray, Associate Director, Scientific Operations will describe encounters with a multitude of diverse and challenging compounds, presenting unique obstacles and prompting innovative solutions to facilitate accurate classification and subsequent biowaivers. The evolution and execution of BCS study design for over 50 compounds will be presented.

10:30 Exploring New Frontiers with BCS Based Biowaivers

Sid Bhoopathy, Ph.D., Chief Operating Officer will explore new frontiers in BCS biowaivers, and potential for extending the applicability/sufficiency of *in vitro* tools beyond conventional boundaries, including possible consideration of transporter substrates for biowaivers and a rational approach for excipient substitution in products of class III drug substances.

Registration Information

\$75.00 for industry representatives

\$25.00 for students, regulatory scientists and academic credentials

Advanced workshop registration required—no on-site enrollment will be accepted

absorption.com/asp

Save your seat today!
Registration is limited.

Workshop organized by Absorption Systems

Absorption Systems offers a comprehensive panel of ADMET assays with screening rigor to GLP. Featured models include evaluating intestinal permeability using human intestinal tissue as well as ocular permeability, distribution, and toxicity. With a focus on maximizing translation and human predictability, Absorption Systems provides the most definitive test systems for transporter substrate and inhibitor assessment to evaluate DDIs. In addition, we utilize tools like the BCS, which has resulted in dozens of successful biowaiver submissions.

Absorption Systems industry reputation for scientific expertise, quality services to clients worldwide, and trusted relationships with regulatory agencies are the products of our unwavering commitment to developing novel research tools.

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