

# 5<sup>th</sup> World Congress on Bioavailability and Bioequivalence Pharmaceutical R&D Summit

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## Strategies for establishing equivalence of complex drug products

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For more than a decade, simple bench-top experiments have been successfully employed to replace clinical bioequivalence according to the Biopharmaceutics Classification System (BCS) for immediate release solid oral dosage forms. However, as drug products continue to increase in complexity, there has been a growing initiative to enhance evaluation by introducing the concepts of quality target product profile (QTPP) and quality by design (QbD). By complementing the traditional paradigm of 'equivalence by testing', the current framework encourages the use of appropriate surrogates to target 'pharmaceutical equivalence by design'. An integrated and dynamic experimental approach, incorporating *in vitro*, *in situ*, *ex vivo*, and *in vivo* non clinical models can be used to evaluate alternate drug delivery routes, compare and optimize formulations (e.g. IVRT), understand the impact of excipient and polymorph substitutions, minimize DoE runs, and guide critical investment decisions. We will explore a rational and multi-pronged approach which relies on validated non-clinical models to bypass clinical studies and/or enhance QbD.

## Biography

Sid Bhoopathy is Chief Operating Officer at Absorption Systems in Exton, PA. He received his Bachelors in Pharmacy from Kakatiya University in 1996 and a PhD, from Virginia Commonwealth University in 2001. As Chief Operating Officer, he directs the convergence of the commercial, technical, and scientific aspects of the company to execute its strategic and tactical growth plans. He possesses a thorough understanding of the science and processes that support lead optimization, candidate selection, and preclinical drug development. In 2011, he was identified as an Emerging Leader by Pennsylvania Bio and in 2013, recognized as a 40 under Forty, Most Talented Young Leader by the Philadelphia Business Journal for his leadership, vision and commitment to the life sciences industry. His current research interests are in the areas of *in vitro* methodologies for assessing bioequivalence, BCS based biowaivers, and drug transporters.

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