

The Evolution of Biopharmaceutics: Risk Assessment and Clinical Relevance

Session 3: Medium Risk Drug Products-How to Use Biopharmaceutics Tool to Understand and Mitigate Risk?

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<i>Breakout C</i>	Xiaoming Xu, PhD	Kevin Wei, Min Sung Sun, Beverly Nickerson, Krutika Harish Jain, David Curran
<i>Breakout D</i>	Joseph Kushner, PhD	Ahmed Zidan, Parnali Chatterjee, Hardikkumar Patel, Ta-Chen Wu, Dorota Danielak, Sanjay Patel, Helana Engman

Session 3: Medium Risk Drug Products

- Medium Risk Drug Products
 - Drug substance: BCS IIb and un-ionizable BCS II? Other borderline conditions?
 - Formulation: IR
 - GI physiology: pH, bile salts, fatty acids
- Breakout Topic C:
 - What Biopharmaceutics Characteristics Differentiate a Medium Risk Product from a Low or High Risk Product?
- Breakout Topic D:
 - What Would be the Appropriate Control Strategy for Medium Risk Products to Ensure Bioperformance?
- Action plan