M-CERSI workshop: Drug Permeability: Best Practices for BCS-based Biowaivers
Virtual Workshop
December 6, 2021

Agenda

8:30 AM – 8:45 AM  
Welcome and Opening Remarks, James Polli, University of Maryland

8:45 AM – 9:00 AM  
Introduction to Permeability for BCS-based Biowaivers, Utpal Munshi, FDA

9:00 AM – 9:50 AM  
Industry Perspectives:

Permeability studies from an innovator perspective for BCS biowaiver support, Jack Cook, Pfizer
Permeability studies from generic perspective for BCS biowaiver support, Katja Kristan & Katja Berginc, Sandoz

9:50 AM – 10:00 AM  
Break

10:00 AM – 10:25 AM  
Industry Case Studies #1: Successful Permeability Studies supporting BCS Biowaiver in NDA (Caco-2, In-Situ, In-Vivo), Ravi Shankar, Pfizer

10:25 AM – 10:50 AM  
Industry Case Studies #2: Successful Permeability Studies supporting BCS Biowaiver in ANDA (Caco-2), Sid Bhoopathy, Absorption Systems

10:50 AM – 11:15 AM  
FDA Case Studies #3: Method Suitability of Caco-2 Cell Models for Drug Permeability Classification, Donna Volpe, FDA

11:15 AM – 11:40 AM  
FDA Case Studies #4: Typical Deficiencies relating to permeability assessment supporting BCS Biowaiver, Haritha Mandula, FDA

11:40 AM – 12:30 PM  
Panel Discussion
Speakers plus Mehul Mehta (FDA), Jan Welink (EMA), Shereeni Veerasingham (HC), and John Gordon (WHO) [Brief remarks from EMA, HC, WHO followed by discussion and Q&A]
Moderator - James Polli, University of Maryland

12:30 PM – 1:30 PM  
Break

1:30 PM – 2:00 PM  
Future of Permeability testing, Jennifer Dressman, Goethe University, Frankfurt, Germany
2:00 PM – 4:00 PM (Each session is 55 minutes in duration and repeated at 3PM with different workshop attendees. All attendees can participate in two breakout sessions, i.e. at 2pm and 3pm.)

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<thead>
<tr>
<th>Breakout Session #1</th>
<th>Breakout Session #2</th>
<th>Breakout Session #3</th>
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<td><strong>In vitro and in silico intestinal permeability methods</strong></td>
<td><strong>Excipient effects on permeability, do we need to be concerned?</strong></td>
<td><strong>Use of label and literature data to designate permeability class</strong></td>
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<td>Co-Leads: Donna Volpe, FDA and Yu Chung Tsang, Apotex</td>
<td>Co-Leads: James Polli, University of Maryland and Pablo Gonzalez, Biopharmaceutical Evaluation Center, Chile</td>
<td>Co-Leads: Shereeni Veerasingham, HC and Susana Almeida, Medicines for Europe</td>
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4:05 PM – 4:20 PM  **Closing Remarks**, Mehul Mehta, FDA