M-CERSI workshop: *Drug Permeability: Best Practices for BCS-based Biowaivers*

**Virtual Workshop**

December 6, 2021

# Agenda

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| 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**<br>***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***<br>**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]**<br>**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.)

| **Breakout Session #1** | **Breakout Session #2** | **Breakout Session #3** |
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| ***In vitro and in silico intestinal permeability methods*** | ***Excipient effects on permeability, do we need to be concerned?*** | ***Use of label and literature data to designate permeability class*** |
| **Co-Leads: Donna Volpe, FDA and Yu Chung Tsang, Apotex** | **Co-Leads: James Polli, University of Maryland and Pablo Gonzalez, Biopharmaceutical Evaluation Center, Chile** | **Co-Leads: Shereeni Veerasingham, HC and Susana Almeida, Medicines for Europe** |

4:05 PM – 4:20 PM ***Closing Remarks*, Mehul Mehta, FDA**