CLOSING REMARKS

M-CERSI Workshop

*Drug Permeability: Best Practices for BCS-based Biowaivers*

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OUTLINE

I. Acknowledgements
II. Workshop Highlights
III. Next Steps
I. Acknowledgments

• **Co-chairs:** Jim Polli and Paul Seo

• **MCERSI colleagues:** Dana Hammell and Ann Anonsen

• **FDA Project Managers:** Tracey Lee and Althea Cuff
I. Acknowledgments

• **Speakers:**
  – Utpal Munshi, Donna Volpe and Haritha Mandula from FDA
  – Jack Cook and Ravi Shankar from Pfizer
  – Katja Kristan and Katja Berginc from Sandoz
  – Sid Bhoopathy from Absorption Systems

• **Special thanks to Professor Jennifer Dressman**
I. Acknowledgments

• **Panelists:**
  – Jan Welink from EMA, John Gordon from WHO, Shereeni Veerasingham from HC, and all speakers
  – Paul Seo for facilitating audience participation

• **Breakout Session Co-Leads:**
  – Donna Volpe and Yu Chung Tsang
  – Jim Polli and Pablo Gonzalez
  – Shereeni Veerasingham and Susana Almeida

• **Breakout Session Scribes:**
  – Haritha Mandula, Jaya Vaidyanathan, Danika Painter
I. Acknowledgments

• **Special thanks to Jim Polli** for wearing multiple hats of running the workshop, moderating the panel, co-leading a breakout session, lining up expert logistical support....
I. Acknowledgments

• And special thanks to all of you for your active participation and contributions in the breakout sessions
II. Workshop Highlights

• Utpal’s concise overview of M9
• Jack’s revealing take on permeability, M9, and wish list!
• Katja’s informative rat perfusion model results
• Ravi’s insight on BCS and global filing challenges of the innovators
• Sid’s real-life examples of Caco-2 method validation issues and promising new IDAS methodology
II. Workshop Highlights

• Donna’s excellent Caco-2 ‘method suitability’ overview
• Haritha’s informative examples and things to pay attention to when filing an application
• Jenny’s exciting overview on the future of permeability measurement
II. Workshop Highlights

• Engaging and informative panel discussion, with unique insight provided by members of EMA, WHO, and HC
II. Workshop Highlights

Breakout sessions

*Breakout Session #1: In vitro and in silico intestinal permeability methods*

- **Objective:** Identify permeability assessment methods other than Caco-2 and how to validate methods
II. Workshop Highlights

**Breakout Session #2: Excipient effects on permeability, do we need to be concerned?**

- **Objective:** Identify excipients that do not need to be Q1 and/or Q2 in various situations, including any limits on excipient amounts
II. Workshop Highlights

**Breakout Session #3: Use of label and literature data to designate permeability class**

- **Objective:** Identify label and literature data types that can serve as primary data to classify permeability as high, and requirements to be met.
III. Next Steps

- We will publish the workshop report very soon.
- Recordings from the 8:30 AM-2:00 PM; 4:05 PM-4:20 PM (main workshop) will be available within ~3 weeks after the workshop. Presentations will also be available once the speakers have given their approval and made any final changes.
- There will be no recordings or slides available from the breakout sessions.
Thank you!!!

December 6, 2021

Mehul Mehta