

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!!!