CERSI
University of Maryland

Creating a Roadmap to Quantitative Systems Pharmacology-Informed Rare Disease Drug Development

Welcome and Opening Remarks

https://cersi.umd.edu/

University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI)

- M-CERSI is an FDA-sponsored center at the Baltimore and College Park campuses of the University of Maryland.

- The mission of the Center is to foster the development of regulatory science – the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products.

CERSI
University of Maryland

M-CERSI workshop website

- Agenda
- Biographies

Within ~2-3 weeks, speaker presentations will be available, along with the recordings from the workshop

https://cersi.umd.edu/event/17946/creating-a-roadmap-to-quantitative-systems-pharmacology-informed-rare--disease-drug-development

CERSI
University of Maryland

- Please use the Chat box for asking questions to the speakers & panelists; please select “Everyone” when asking your questions so everyone can see the questions. If you have questions for a specific speaker, put their name in parentheses. We will do our best to address as many questions as we can in the allotted time.
- Closed Captioning is provided. To turn on closed captioning, go to the Live Transcript^ at the bottom of the screen and click on ^ and select the option, Show Subtitles. The closed captioning will show up along the bottom of your screen.

CERSI
University of Maryland

Upcoming M-CERSI In-person Workshops

May 23-24: Drug Dissolution in Oral Drug Absorption

Registration closes May 12

https://www.pharmacy.umaryland.edu/centers/cersievents/dissolution2023/

August 29-31: Physiologically Based Biopharmaceutics Modeling (PBBM) Best Practices for Drug Product Quality

Registration open

https://www.pharmacy.umaryland.edu/centers/cersievents/PBBM2023/

CERSI
University of Maryland

Meeting Chairs from FDA

Robert Schuck, PharmD, PhD
Deputy Director
DTPM | OCP | CDER | FDA
Deputy Director of the Division of Translational and Precision Medicine (DTPM) in the Office of Clinical Pharmacology (OCP) at the FDA. The division focuses on regulatory review, research, and policy development in the areas of pharmacogenomics, biomarker qualification, drugs for rare diseases and inborn errors of metabolism, and genetically targeted therapies.
Before joining the FDA in 2013, he received his PharmD from the University of Michigan College of Pharmacy in 2008 then completed his PhD in Pharmaceutical Sciences at the University of North Carolina Eshelman School of Pharmacy in 2013.

Jane P.F. Bai, PhD
Expert Regulatory Scientist
DARS | OCP | CDER | FDA
Expert Regulatory Scientist with expertise in systems pharmacology at the FDA. Dr. Bai has served on the NIH National Institute of Biomedical Imaging and Bioengineering Interagency Modeling and Analysis Group as one of three FDA representatives since 2021. Dr. Bai received a Master's degree in Applied Mathematics in 1990, and PhD in Pharmaceutics in 1990 from the University of Michigan, Ann Arbor, Michigan. Dr. Bai was on the faculty of Pharmaceutics Department of the University of Minnesota Twin Cities between 1990-1996. From 1996 to 2004, she was an entrepreneur developing and licensing to several pharmaceutical companies an in-silico software, OraSpotter®, for predicting the fraction dose absorbed in humans. Dr. Bai has published 80 peer-reviewed papers and book chapters and co-edited the book entitled "Systems Medicine", which was published by Springer Nature in 2022.

CERSI
University of Maryland