PBSS
Pharmaceutical & BioScience Society
San Francisco Bay

Nov 13th, 2023
8:45 am-4:50 pm, PT

San Francisco Bay Area:
Crowne Plaza Foster City
Webcast to non-local attendees

Clinical Pharmacology Across the Drug Development Continuum:

Key Clinical Studies, Modeling & Simulation to Support Drug Approval and Labeling

Organizers: Jennifer Dong (EMD Serono), Lisa Benincosa (Allucent), Ashley Lennox (Allucent), Manushree Bharadwaj (Allucent), Snow Ge (BridgeBio Pharma), Shichang Miao (Consultant)

Luzelena Caro, PhD
Senior Director, Clinical Pharmacology, Gilead

The Role of Clinical Pharmacology in Drug Development

Yuan Zhao, MS, PhD
Scientific Director, EMD Serono

Clinical Pharmacologic Evaluation of Population Variability in Global Drug Development

Neha Bhise, PhD
Sr. Clinical Pharmacologist, Allucent

Clinical Pharmacology Studies to Support Filing Packages and Labeling

Joy Hsu, MS, PhD
Distinguished Scientist, Clinical Pharmacology, Genentech

Application of Model-Informed Drug Discovery and Development in the Pharmaceutical Field

Raj Madabushi, PhD
Associate Director, Guidance and Scientific Policy, Office of Clinical Pharmacology, OTS/CDER/FDA

Clinical Pharmacology Considerations in Regulatory Evaluation

Major Sponsors

Quotient Sciences

Molecule to cure. Fast.™

Fortrea

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Time (PT)	Topic	Presenter
8:45-9:00 am	PBSS Welcome and Introduction	Snow Ge, BridgeBio Pharma
9:00-10:15 am	The Role of Clinical Pharmacology in Drug Development	Luzelena Caro, PhD, Senior Director, Clinical Pharmacology, Gilead
10:15-10:25 am	Major Sponsor Presentation	Quotient Sciences
10:25-10:45 am	Break and Vendor Show	-
10:45-12:00 pm	Clinical Pharmacologic Evaluation of Population Variability in Global Drug Development	Yuan Zhao MS, PhD, Scientific Director, EMD Serono
12:00-1:00 pm	Lunch	Sponsor, TBD
1:00-2:00 pm	Clinical Pharmacology Studies to Support Filing Packages and Labeling	Neha Bhise, PhD Sr. Clinical Pharmacologist, Allucent
2:00-3:00 pm	Application of Model-Informed Drug Discovery and Development in the Pharmaceutical Field	Joy Hsu, MS, PhD, Distinguished Scientist, Clinical Pharmacology, Genentech
3:00-3:10 pm	Major Sponsor Presentation	Fortrea
3:10-3:35 pm	Break	-
3:35-4:20 pm	Clinical Pharmacology Considerations in Regulatory Evaluation	Raj Madabushi, PhD, Associate Director, Guidance and Scientific Policy, Office of Clinical Pharmacology, OTS/CDER/FDA
4:20-4:50 pm	Panel Discussion	All Speakers
4:50-5:50 pm	Happy Hour	Sponsor, Alturas Analytics

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