

In-Person Workshop

Jan. 19, 2024 8:45 am-5:00 pm PST

ADME/DMPK Studies for IND and NDA Filing for Small Molecules: Nuts, Bolts and Best Practices

Organizers: Simon Wong (Aditum Bio), Jan Wahlstrom (Amgen)



San Francisco Bay Area: Crowne Plaza Foster City
Available as webcast to other PBSS chapters



Simon Wong, PhD
VP Nonclinical Development and Clinical Pharmacology, Aditum Bio

- Overview of CTD Sections 2.6.4, 2.6.5 and Module 4
- Metabolism Based Drug-Drug Interactions



Jan Wahlstrom, PhD
Executive Director, Amgen

- Overview of CTD Sections 2.6.4, 2.6.5 and Module 4
- Human ADME-Case Studies-Phenotyping



Sean Xiaochun Zhu, PhD
Scientific Director, Takeda

Preclinical Metabolism and Victim Drug-Drug Interactions



Cyrus Khojasteh, PhD
Senior Director, Genentech

In vitro Metabolism, Clinical MetID and Metabolites in Safety Testing (MIST)



Werner Rubas, PhD
Vice President, Preclinical Development, Sutro Biopharma, Inc.

IND Enabling Studies for Antibody-Drug Conjugates



Xinning Yang, PhD
Policy Lead of Clinical Pharmacology, FDA

FDA Experience on IND/NDA ADME Studies



Ilaria Badagnani, PhD
Previously Senior Director and Head of DMPK, Theravance Biopharma Inc

Case Study: Izencitinib Disposition, Metabolism, and Transporter/Metabolism DDI Risk Assessment in Humans



Upendra Dahal, PhD
Associate Director, Amgen

ADME Package of Covalent Drug Sotorasib

Major Sponsors



Q² Solutions®



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Registration: <https://www.pbss.org/asp/homeSF.aspx>

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Time (PST)	Topic	Presenter
8:45 - 9:00 am	PBSS Welcome and Introduction	Shichang Miao (PBSS)
9:00 - 9:30 am	Overview of Sections 2.6.4, 2.6.5 and Module 4	Simon Wong (Aditum Bio) & Jan Wahlstrom (Amgen)
9:30 - 10:10 am	Preclinical Metabolism and Victim Drug-Drug Interactions:	Sean Xiaochun Zhu, PhD, Scientific Director, Takeda
10:10 - 10:20 am	Major Sponsor Presentation	Q2 Solutions
10:20 - 10:40 am	Break and Vendor Show	-
10:40 - 11:20 am	In vitro Metabolism, Clinical MetID and MIST	Cyrus Khojasteh, PhD, Senior Director, Genentech
11:20 - 11:50 am	Human ADME – Case Studies – Phenotyping	Jan Wahlstrom, PhD, Executive Director, Amgen
11:50am-12:30 pm	Translation of DDI Perpetrator to IND/NDA	Simon Wong, PhD, VP Nonclinical Development and Clinical Pharmacology, Aditum Bio
12:30 - 1:20 pm	Lunch	Sponsored by Velocity Labs
1:20 - 2:00 pm	FDA Experience on IND/NDA ADME Studies	Xinning Yang, PhD, Policy Lead of Clinical Pharmacology, FDA
2:00 - 2:40 pm	IND Enabling Studies for Antibody-Drug Conjugates	Werner Rubas, PhD, Vice President, Preclinical Development, Sutro Biopharma, Inc.
2:40 - 2:50 pm	Major Sponsor Presentation	Fortrea CRO
2:50 - 3:15 pm	Break and Vendor Show	-
3:15 - 3:50 pm	Case Study: Izcenitib Disposition, Metabolism, and Transporter/Metabolism DDI Risk Assessment in Humans	Ilaria Badagnani, PhD, Previously Senior Director and Head of DMPK, Theravance Biopharma Inc
3:50 - 4:30 pm	ADME Package of Covalent Drug Sotorasib	Upendra Dahal, PhD, Associate Director, Amgen
4:30 - 5:00 pm	Panel Discussion	All Speakers
5:00 - 6:00pm	Happy Hour	Sponsored by Alturas Analytics

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