21 May, 2024
8:45 am - 5:30 pm PT

PBSS
Pharmaceutical & BioScience Society
San Francisco Bay

Nonclinical Safety Studies for IND and NDA Filing for Small Molecules: Nuts, Bolts and Best Practices

Organizer: Doris Zane, PhD, DABT, Executive Director, Nonclinical Safety, Gilead Sciences

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

Joanne Birkebak, DVM, DABT
Independent Consultant

Introduction to Nonclinical Safety: Who We Are and What We Do

Toufan Parman, PhD, DABT
Senior Director of Nonclinical Safety Evaluation, **Sangamo Therapeutics**

Genetic Toxicology and Carcinogenicity: What Do We Need and When Do We Need It?

Joel Bercu, PhD, MPH, DABT
Executive Director, **Gilead Sciences**

Introduction and Occupational Toxicology

Melisa Masuda-Herrera, MS, DABT
Senior Associate Scientist, **Gilead Sciences**

Environmental Toxicology

Dinah Misner, PhD, DABT, DSP
VP, **Aligos Therapeutics**

Safety Pharmacology Studies for Discovery and Development of Small Molecules for INDs/NDAs

Ellen McGlinchey, PhD
Senior Project Toxicologist (Sr. Research Scientist II), Nonclinical Safety and Pathobiology, **Gilead Sciences**

Developmental and Reproductive Toxicology (DART) Studies: Small Molecule Designs, Endpoints, and Case Studies

Alejandra Trejo-Martin, MS
Senior Associate Scientist, **Gilead Sciences**

Toxicological Assessment of Impurities

Jessica Hawes Oliphant, PhD
Deputy Director, Division of Systems Biology, National Center for Toxicological Research, **FDA**

Nonclinical Regulatory Perspectives on Small Molecule Drug Development Programs

Major Sponsors

Emery PHARMA

药明康德 WuXi AppTec

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Time (PST)	Topic	Presenter
8:45 - 9:00 am	PBSS Welcome and Introduction	**Shichang Miao**, PhD, President, PBSS; Doris Zane, PhD, DABT, Executive Director, Nonclinical Safety, **Gilead Sciences**
9:00 - 10:00 am	Introduction to Nonclinical Safety: Who We Are and What We Do	**Joanne Birkebak**, DVM, DABT, **Independent Consultant**
10:00 - 11:00 am	Safety Pharmacology Studies for Discovery and Development of Small Molecules for INDs/NDAs	**Dinah Misner**, PhD, DABT, DSP, VP, **Aligos Therapeutics**
11:00 -11:10 am	Major Sponsor Presentation	Emery Pharma
11:10 -11:30 am	Break and Vendor Show	-
11:30 am -12:30 pm	Genetic Toxicology and Carcinogenicity: What Do We Need and When Do We Need It?	**Toufan Parman**, PhD, DABT, Senior Director of Nonclinical Safety Evaluation, **Sangamo Therapeutics**
12:30 - 1:30 pm	Lunch	Sponsor (Pharmaron)
1:30 - 2:30 pm	Developmental and Reproductive Toxicology (DART) Studies: Small Molecule Designs, Endpoints, and Case Studies	**Ellen McGlinchey**, PhD, Senior Project Toxicologist (Sr. Research Scientist II), Nonclinical Safety and Pathobiology, **Gilead Sciences**
2:30 - 3:30 pm	Environmental and Occupational Toxicology	**Joel Bercu**, PhD, MPH, DABT, Executive Director; **Melissa Masuda-Herrera**, MS, DABT, Senior Associate Scientist; **Alejandra Trejo-Martin**, MS, Senior Associate Scientist, Environmental and Occupational Toxicology, **Gilead Sciences**
3:30 - 3:40 pm	Major Sponsor Presentation	WuXi AppTec
3:40 - 4:00 pm	Break and Vendor Show	-
4:00 - 5:00 pm	Nonclinical Regulatory Perspectives on Small Molecule Drug Development Programs	**Jessica Hawes Oliphant**, PhD, Deputy Director, Division of Systems Biology, National Center for Toxicological Research, **FDA**
5:00 - 5:30 pm	Panel Discussion	All Speakers
5:30 - 6:30 pm	Happy Hour	Sponsor (Veloxity Labs)

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