



April 30, 2024 8:45 am-5:30 pm Pacific Time

Small Molecule Preclinical Development and IND Filing: Nuts, Bolts and Best Practices

Organizers: Sanjeev Thohan, PhD (SARx consulting), Robyn Rourick, MSc (Genentech), Lilia Koriazova, PhD (Erasca, Inc.)

Hilton San Diego/Del Mar, 15575 Jimmy Durante Blvd, Del Mar, CA 92014



Aziz Alam, MS Sr Director, Regulatory Affairs, Alterome Therapeutics

IND Filing and Interaction With FDA



Elisabeth Gardiner, PhD President, EMMG Consulting

Non-Clinical Pharmacology and Pharmacokinetics



Sanjeev Thohan, PhD Founder, SARx Consulting

Non-Clinical Drug Safety



Preetanshu Pandey, PhD Head of CMC, Boundless Bio

Chemistry, Manufacturing, and Controls



Ken Kobayashi, MD, FACP Chief Medical Officer, Pyxis Oncology



Grace Furman, PhD, DABT President & CEO, **Paracelsus, Inc.**

Clinical Development

Preclinical Drug Development From a Regulatory Perspective

Sponsor

PHARMACEUTICS / MANUFACTURING

Registration: <u>http://www.pbss.org/aspx/homeSD.aspx</u>



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Time (PST)	Topic & Presenter
8:45-9:00 am	PBSS Welcome and Introduction (Robyn Rourick, MSc, Sr. Director, Genentech and PBSS-SD Co-Chair)
9:00-9:40 am	IND Filing and Interaction With FDA (Aziz Alam, MS, Sr. Director, Alterome Therapeutics Inc.)
9:40-10:45 am	Non-Clinical Pharmacology & Pharmacokinetics (Elisabeth Gardiner, PhD, President, EMMG Consulting)
10:45-10:55 am	Major Sponsor Presentation
10:55-11:10 am	Break & Vendor Show
11:10 am-12:10 pm	Non-Clinical Drug Safety (Sanjeev Thohan, PhD, Founder, SARx Consulting)
12:10-1:00 pm	Lunch
1:00-1:45 pm	Non-Clinical Drug Safety (cont'd)
1:45-2:45 pm	Chemistry, Manufacturing, and Controls (Preetanshu Pandey, PhD, Head of CMC, Boundless Bio)
2:45-2:55 pm	Major Sponsor Presentation (AustinPx)
2:55-3:15 pm	Break & Vendor Show
3:15-4:15 pm	Clinical Development (Ken Kobayashi, MD, FACP, Chief Medical Officer, Pyxis Oncology)
4:15-4:55 pm	Preclinical Drug Development From a Regulatory Perspective (Grace Furman, PhD, President & CEO, Paracelsus, Inc.)
4:55-5:30 pm	Panel Discussion
5:30-6:30 pm	Happy Hour (Sponsor: Alturas Analytics)

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