

Workshop

Antibody Preclinical Development & IND Filing: Nuts, Bolts, Best Practices and Regulatory Strategies



Scientific Program Partner

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Organizers: Laurence Fayadat-Dilman, PhD, (Merck); Ayse Meric Ovacik, PhD (Genentech); Lilia Koriazova, PhD (Erasca); Udaya Rangaswamy, PhD (Rondo Therapeutics); James Ernst, PhD (Xencor); Kristen McPike (TAbS); Stephanie Casey Parks, PhD, (Amgen)

Thursday, 11 June 2026

8:45 am - 5:30 pm Pacific Time

NEW! Hilton San Francisco Airport Bayfront
 (600 Airport Blvd., Burlingame, CA 94010)



Registration:

<https://www.pbss.org/eventDetails/1038>

In-Person:

Regular \$295, Academic or Self Paying: \$45;

Webcast (non-local to SF-Bay):

Regular \$295, Academic or Self Paying: \$125



Laurence Fayadat-Dilman, PhD

Executive Director, Discovery Biologics. Head of Protein Sciences, Merck



Ayse Meric Ovacik, PhD

Distinguished Scientist and Director, Genentech



Stephanie Casey Parks, PhD

Senior Principal Scientist, Amgen



Jay Tibbitts, DVM, PhD

VP, Nonclinical Development, Lycia



Kapil Gadkar, PhD

Senior Fellow & Senior Director, Development Sciences, Genentech



Smita Salian-Mehta, PhD, DABT, ERT

Principal Scientist II, Gilead



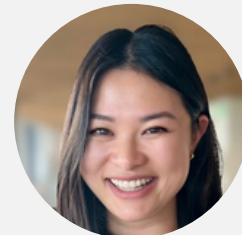
Lilia Koriazova, PhD

Sr Director, Biologics Pharmaceutical Sciences, Erasca



Sara Glickstein Bar-Zeev, PhD

Principal Clinical Scientist, Genentech



Lauren Dam, MS

Associate Director, Regulatory Affairs, Genentech



Leah Rosenfeld, PhD

Senior Toxicologist, FDA

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Event Major Sponsors:



Workshop

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PBSS
Pharmaceutical & BioScience Society
San Francisco Bay

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Time (PST)	Topic	Presenter(s)
8:45 AM - 9:00 AM	Welcome	PBSS & TABS
9:00 AM - 9:35 AM	Overview of Antibody-based therapeutics: Structure, Generation, Design, and Optimization	Laurence Fayadat-Dilman, PhD, Executive Director, Discovery Biologics. Head of Protein Sciences, Merck
9:35 AM - 10:10 AM	Overview of Preclinical Development and IND Filing Requirements for Antibody-based Therapeutics	Ayse Meric Ovacik, PhD, Distinguished Scientist and Director, Genentech
10:10 AM - 10:45 AM	Non-clinical Pharmacology Considerations for Biologics	Stephanie Casey Parks, PhD, Senior Principal Scientist, Amgen
10:45 AM - 10:55 AM	Major Sponsor Presentation	BioAgilytix
10:55 AM - 11:15 AM	Break & Vendor Show	-
11:15 AM - 11:50 AM	Pharmacokinetic/Pharmacodynamic and Bioanalytical Considerations for Successful IND Filings	Jay Tibbitts, DVM, PhD, VP, Nonclinical Development, Lycia
11:50 AM - 12:25 PM	Preclinical toxicology Studies and Considerations for Biotherapeutic IND Submissions	Smita Salian-Mehta, PhD, DABT, ERT, Principal Scientist II, Gilead
12:25 PM - 1:25 PM	Lunch	LUNCH SPONSOR
1:25 PM - 2:00 PM	IND-enabling CMC Activities for Therapeutic Antibodies	Lilia Koriazova, PhD, Sr Director, Biologics Pharmaceutical Sciences, Erasca
2:00 PM - 2:35 PM	PK/PD ClinPharm & Dose Projection Deeper Dive	Kapil Gadkar, PhD, Senior Fellow & Senior Director, Development Sciences, Genentech
2:35 PM - 3:10 PM	Clinical Development Plan	Sara Glickstein Bar-Zeev, PhD, Principal Clinical Scientist, Genentech
3:10 PM - 3:20 PM	Major Sponsor Presentation	SGS North America
3:20 PM - 3:40 PM	Break, Vendor Show	-
3:40 PM - 3:50 PM	Raffle	-
3:50 PM - 4:25 PM	Regulatory Strategies and Interactions with FDA: Industry Perspective & How to Prepare for FDA Meetings	Lauren Dam, MS, Associate Director, Regulatory Affairs, Genentech
4:25 PM - 5:00 PM	INDs for biologics From The regulatory Perspective: The Do's and Don'ts for a Successful IND Application	Leah Rosenfeld, PhD, Senior Toxicologist, FDA
5:00 PM - 5:30 PM	Panel Discussion	All speakers
5:30 PM - 6:30 PM	Happy Hour	



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Exhibitors:



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