## THE 6TH KAPAL ANNUAL CONFERENCE 2022

Gaithersburg Marriott Washingtonian Center 9751 Washingtonian Blvd, Gaithersburg, MD 20878

## Program-at-a-Glance

Thursday, November 17			
5:00 – 6:00 pm	Registration & Networking		
6:00 – 6:20pm	Opening Remarks KAPAL Byung Ha Lee (President, KAPAL)		
	Embassy of Republic of Korea		
	<b>State of Maryland</b> Jimmy Rhee (Special Secretary, Governor's Office, Small, Minority & Women Business Affairs)		
6:20 – 6:30 pm	Group Photo		
6:30 – 7:40 pm	Dinner		
7:40 – 8:00 pm	Hosting Sponsor Presentation Psomagen ISU_ABXIS		
8:00 – 9:00 pm	Keynote presentation I (Day1)		
	Adopting Orphan Diseases-It Take a Village Insook Kim Ph.D. (Team Lead, Clinical Pharmacology, CDER, FDA)		
	Key IND-Enabling Nonclinical Studies for Rare Diseases: A Regulatory perspective Yangmee Shin Ph.D. (Pharmacologist, CDER, FDA)		
	Q&A		
9:00 – 10:30 pm	Networking (Beer & Wine) & End of Day 1		

Friday,	November 18			
8:00 - 8:20 am	Registration / Breakfast			
8:20 - 9:00 am	Session 1. Company Presentation "Proteomics in Oncology Clinical Guidance" Sheeno Thyparambil (mProbe) Company 2 Company 3 Company 4			
9:00 – 9:30 am	Keynote presentation II (Day2) "Building a biotech company: MyoKardia Story" June H, Lee, MD FACCP (Venture Partner, 5AM Ventures Board Director, Cincor Pharmaceuticals, Teneya Therapeutics, GenEdit, Eledon Therapeutics Scientific Advisory Board, Foresite Labs Adjunct Professor, UCSF School of Medicine)			
9:30 – 10:10 am	Session 2. BioTech Support Programs "Government Support Programs in Fairfax County" Christy Youk (International Business Investment Manager, Fairfax County Economic Development Authority) "Accelerating Drug Discovery to Commercialization from Korea to the U.S." Ernesto Chanona (Director of Business Development & Government Affairs, CSSi LifeSciences)	10:00 – 3:00 pm	Parallel Session: ABES (Annual Bioscience and Engineering Symposium) by NIH- KSA (NIH-Korean Scientist Association)	
10:10 - 10:20 am	Coffee break			

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10:20 - 11:20 am	Session 3. KHIDI USA K-Blockbuster K-Blockbuster Project (by KHIDI USA) Huons USA (Jay Choi) Welt (Sean G. Kang) BW Biomed (Jung-hoon Woo)		
11:20 - 12: 20 pm	Session 4. Panel Discussion on Drug Development Strategy "US Healthcare and Pharmaceutical Reimbursement Systems and Impacts on Your Development Strategy"		
12:20 - 1:00 pm	Lunch		
1:00 - 2:00 pm	Session 5. Cell and Gene Therapy Speaker 1: "Market trends in cell and gene therapy" Speaker 2: "GMP for cell and gene therapy"		
2:00 - 3:40 pm	Session 6. Grant for US Business: Small Business Innovation Research (SBIR) "Overview of NIH SBIR" Meena U. Rajagopal (NCATS) "NCI specific SBIR" Jian Lou (NCI) "NHLBI specific SBIR" Stephanie Davis (NHLBI) "Review process and point" Allen Richon (NIH/CSR)		
3:40 - 4:00 pm	Coffee brea	k	
4:00 - 5:30 pm	Session 7. Digital Health "Evolution of PCR - Concept of Digital PCR and Its Application" Do Young Lee (CEO of OPTOLANE) "New Paradigm Approach of Drug Discovery - Al Drug Discovery Platform as a Cloud Service" Kilyoung Kim (President of Syntekabio USA) "FDA's Evolving Policy Framework for Digital Health Products" Sung Park (FDA lawyer, Reed Smith)		Career Development/Job fair

5:30 - 9:00 pm	KPBMA/KHIDI Special Session		
	Greeting		
	<b>Regenerative medicine cellular therapy regulation and research</b> Kyung Eun Sung, Ph.D. (Senior Investigator, CBER, FDA)		
	Real-World Data and Real-World Evidence in Drug Development: The opportunities and challenges Joo-Yeon Lee, Ph.D		
	(Senior Statistical Reviewer, CDER, FDA)		
	NIH Grants and Funding Mechanisms Young S. Oh, Ph.D. (Deputy Branch Chief, NHLBI, NIH)		
	Q&A		
	Dinner/Networking		
9:00 - 9:10 pm	Closing Remarks		