2023 NIFDS-PMDA-USP Workshop for Advanced Therapies

- From November 30th to December 1st, 2023 (09:00-14:00, KST)
- Hybrid on-/off-line format, ※ On-site venue: Sofitel Ambassador Seoul Hotel, Seoul, Korea

DAY 1 11. 30 (Thur. 09:00-14:00)				
08:30 - 09:00	Registration			
09:00 - 09:20	Opening Remarks / Greetings / Photo	**Younjoo Park**	(Director General, NIFDS)	on-site
		Hiroyuki Arai	(Executive Director, PMDA)	recording
		Fouad Atouf	(Senior Vice President, USP)	virtual
Session 1. Regulatory Convergence for Advanced Therapy		Moderator: **Misun Park** (NIFDS)		on-site
09:20 - 09:40	USA	**Ramjay Vatsan**	(Asso. Dir. DCGT/OTAT/CBER, FDA)	recording/ virtual
09:40 - 10:00	EMA	**Nino Mihokovic**	(Quality Specialist, EMA)	virtual
10:00 - 10:20	Korea	**Mira Choi**	(Dir., NIFDS)	on-site
10:20 - 10:40	Japan	**Jun Matsumoto**	(Review Dir. of GCT, PMDA)	on-site
10:40 - 10:55	Q&A			
10:55 - 11:10	Coffee break			
Session 2. Reality Gap between Regional/Global Guidelines and Drug Approval Process Moderator: **Christopher Bravery** (USP BIO5 Expert Committee)				on-site
11:10 - 11:35	Industry perspectives on the market approval process of Advanced Therapy products in South Korea and Japan	**Florence Salmon** (VP, Hookipa Pharma)		virtual
11:35 - 12:00	Regulatory approval process of Luxturna in Japan	**Shunsuke Tominaga** (RA Head, NSX/MDMP, Novartis Pharma Japan)		on-site
12:00 - 12:25	Regional Lessons Learned for Global Marketing Applications and Approvals for Allogeneic Cell Therapy	**Amy M. McCord** (Dir. Global Reg. CMC, Cell Therapies, Takeda Pharma)		virtual
12:25 - 12:40	Q&A and closing	**Christopher Bravery**	(USP BIO5 EC)	on-site
12:40 - 14:00	Networking luncheon			

DAY2 12. 1 (Fri. 09:00-14:00)				
09:00 - 09:10	Greeting / Photo	**Ben Clarke**	(USP)	on-site
Session 3. Early Development and Quality Control Strategies				
Session 3-1: Quality Control		Moderator: **Shinichi Noda** (PMDA)		on-site
09:10 - 09:30	Process Characterization for Establishing CPPs during CAR-T Product Development	**Mehrshid Alai-Safar** (VP, Global Reg., Kite Pharmaceuticals)		on-site
09:30 - 09:50	Advanced 3D Bioprinting Product Combined with Stem cells	**Sung Won Kim**	(Prof. Catholic Univ.)	on-site
09:50 - 10:10	Challenges of Developing CQA – iPSC-derived Cardiomyocyte Sheet	**Masao Sasai**	(Prof. Osaka Univ.)	on-site
10:10 - 10:25	Q&A			
10:25 - 10:40	Coffee break			
Session 3-2: Pre-clinical Safety Study		Moderator: **Mehrshid Alai-Safar** (Kite Pharma)		on-site
10:40 - 11:10	Biodistribution of Cell Therapy Products	**Yoshiteru Kamiyama** (Senior Dir. Astellas Pharma)		virtual
11:10 - 11:30	Organoids-based Evaluation Methods	**Jong-man Yoo** (Prof./CEO, Organoid Sciences)		on-site
11:30 - 11:50	Genomic Stability and Tumorigenicity	**Yoji Sato**	(Head, Division of Drugs, NIHS)	on-site
11:50 - 12:05	Q&A			
12:05 - 12:15	Closing Remark	**Soo Jung Sohn**	(Dir. General of PMDR, NIFDS)	on-site
12:15 - 14:00	Networking luncheon			