

Date: November 18th to November 19th
Venue: Tokyo Port City Takeshiba Port Hall

Day 1: November 18th

		Lecture Time		Q&A			
9:30	10:00	30min	0min	Reception			
10:00	10:15	15min	0min	Opening Remarks		Professor Shingo Sakurai	Tokyo University of Science, Laboratory of Pharmaceutical Quality Design and GMP
10:15	16:50	Current and Future Regulations					
10:15	10:50	30min	5min	Presentation 1	Keynote speech:	Yumiko Nomura, Director Medical Devices Review and Licensing Division, Ministry of Health, Labor and Welfare	Current situation regarding regenerative medicine products: from the perspective of the Pharmaceuticals and Medical Devices Act
10:50	11:25	30min	5min	Presentation 2		Ayaka OKAMOTO, Ph.D. PMDA Regenerative Medicine Products Review Division	Key Quality Issues in the Review of Regenerative Medical Products
11:25	12:25	60min	Lunch				
12:25	13:15	45min	5min	Presentation 3		Dr. Yoji Sato Deputy Director General National Institute of Health Sciences	Draft Revision of the Japanese Standards for Biological Raw Materials
13:15	13:50	30min	5min	Presentation 4		Dr. So-Ra PARK President & Founder, Regenerative Medicine Acceleration Foundation Professor, College of Medicine, Inha University	An Overview of the Advanced Regenerative Medicine Regulation and Industry in Korea
13:50	14:25	30min	5min	Presentation 5		Dr. David Chang CEO Taiwan Bio-Manufacturing Corporation (TBMC)	Taiwan ATMP ecosystem and enabling CDMO"
14:25	15:10	45min	Coffee Break				
Initiatives related to ATMP at PDA Headquarters							
15:10	15:45	30min	5min	Presentation 6		Friedrich von Wintzingerode, PhD Chair of ATMP AB at PDA Headquarters Roche,	"PDA Headquarters' Initiatives Regarding ATMP"
15:45	16:20	30min	5min	Presentation 7		Darius Pillsbury pH.D ValSource,	Points to Consider(PtC) No. 11: Development, Classification, Manufacture, Control, and Testing of Plasmids and Vectors Used in ATMP Production
16:20	16:55	30min	5min	Presentation 8		Takehiro Okumura Ph.D Co-Chair of ATMP IG at PDA Headquarters. Alloy Therapeutics	"Introduction to Points to Consider Regarding ATMP Raw Material Management"
17:00	19:00	Social gathering (standing)					

Day 2: November 19th

8:30	9:00	30min	0min	受付			
9:00	10:40	Product Development					
9:00	9:35	30min	5min	Presentation 10		Kazumi Sawaguchi SanBio Co. Ltd., Corporate Officer, Head of Regulatory Affairs & Quality Compliance, Marketing Supervisor-General	Development of Regenerative Medicine Product "A k uugo
9:35	10:10	30min	5min	Presentation 11		Kiwamu Imagawa J C R Pharmaceuticals Co., Ltd. / AlliedCel Corporation	Development and Post-marketing Issues of Japan's First Allogeneic Regenerative Medicine Product "TEMCELL ® HS Injection
10:10	10:20	10min	Rest		J-PDA presentation		
10:20	10:55	30min	5min	Presentation 12		Yasuhiro Ikematsu Japan PDA Pharmaceutical Society, Chair of Aseptic Product GMP Committee Associate Professor, Graduate School Engineering at The University of OSAKA	The Use of Rapid Microbiological Methods (RMM) for Sterility Testing in ATMPs Manufacturing
10:55	11:30	30min	5min	Presentation 13		Atsushi Kaneishi Japan PDA Pharmaceutical Society, Aseptic Product GMP Committee ROHTO Pharmaceutical Co., Ltd. Regenerative Medicine Research Planning Division	Considerations for Aseptic Cleaning Based on Visualization of Residual Stuff in Grade A Areas of ATMPs Manufacturing
11:30	12:30	60min	Lunch				
Session 3				Facility design & CCS			
12:30	13:05	30min	5min	Presentation 14		Richard Denk Senior Consultant Aseptic Processing & Containment SKAN,	A training on the Facility Design for ATMPs for inspector
13:05	13:40	30min	5min	Presentation 15		Dr. Ruben van der Galien GE Healthcare,	Contamination Control Strategy for ATMPs.
Issues surrounding containers							
13:40	14:15	30min	5min	Presentation 16		Mr. Noba Ebaid afeguarding Pharmaceuticals PTI	The Critical Role of Container Closure Integrity in Cell & Gene Therapy (CGT) and Biologic Packaging
14:15	14:50	30min	5min	Presentation 17		Takahiro Ogasawara Director of Product Development and Strategic Planning Office Japan Tissue Engineering Co., Ltd. (J-TEC)	Until it reaches the patient: The reality of containers, packaging, and transportation of regenerative medicine products
14:50	15:20	Coffee Break					
15:20	16:10	45min	5min	Presentation 18	Special Lecture	Stephan O. Krause, PhD Executive Director Analytical Strategy, BMS Cell Therapies	Aligned Control Strategy Proportions and Staging Opportunities—Concept and Execution Roadmap for an Enhanced and Integrated Analytical Control Strategy for Autologous Cell Therapies
16:10	17:00	45min	5min	Presentation 19	Special Lecture	Professor Masahiro Kino-oka Graduate School of Engineering, at The University of OSAKA	Development of smart cell manufacturing based on the QbD approach
17:00	17:10			Summary & Closing remarks		Richard Denk	