

Day 1: November 18th

start	finish	topic		speaker
9:30	10:00	Reception		
10:00	10:15	Opening Remarks		Professor Shingo Sakurai Tokyo University of Science, Laboratory of Pharmaceutical Quality Design and
Session 1 <Current and Future Regulations>				
10:15	10:50	Keynote speech:	Current situation regarding regenerative medicine products: from the perspective of the Pharmaceuticals and Medical Devices Act	Yumiko Nomura Director Medical Devices Review and Licensing Division, Ministry of Health, Labor and Welfare
10:50	11:25		Key Quality Issues in the Review of Regenerative Medical Products	Ayaka OKAMOTO Ph.D. PMDA Regenerative Medicine Products Review Division
11:25	12:25	Session by Sponser	Introduction and Future Outlook of Electronic Records in Regenerative Medicine Facilities	11:35 - 11:50 Körber Japan K.K.
12:25	13:15		Draft Revision of the Japanese Standards for Biological Raw Materials: Proposals from the AMED Working Group	Dr. Yoji Sato Deputy Director General National Institute of Health Sciences
13:15	13:50		An Overview of the Advanced Regenerative Medicine Regulation and Industry in Korea	Dr. So-Ra PARK President & Founder, Regenerative Medicine Acceleration Foundation
13:50	14:25		Taiwan ATMP Ecosystem and Enabling CDMO	Dr. David Chang CEO Taiwan Bio-Manufacturing Corporation (TBMC)
14:25	15:10	Coffee Break		
Session 2 <Initiatives related to ATMP at PDA Headquarters>				
15:10	15:45		“PDA Headquarters” Initiatives Regarding "ATMP"	Friedrich von Wintzingerode PhD Chair of ATMP AB at PDA Headquarters Roche,
15:45	16:20		Points to Consider for the Use of Plasmids and Viral Vectors in ATMP Production	Darius Pillsbury pH.D ValSource,
16:20	16:55		PDA Points to Consider No.13 Materials in ATMP Manufacturing	Takehiro Okumura Ph.D Co-Chair of ATMP IG at PDA Headquarters.
17:00	18:30	Social gathering (standing)		

Day 2: November 19th

start	finish	topic	speaker
8:30	9:00	Reception	
Session 3 <Product Development>			
9:00	9:35	Development of Regenerative Medicine Product "Akugo"	Kazumi Sawaguchi SanBio Co. Ltd., Corporate Officer, Head of Regulatory Affairs & Quality Compliance, Marketing Supervisor-
9:35	10:10	Development and Post-marketing Issues of Japan's First Allogeneic Regenerative Medicine Product "TEMCELL® HS Injection"	Kiwamu Imagawa J C R Pharmaceuticals Co., Ltd. / AlliedCel Corporation
10:10	10:20	Break	
Session 4 <J-PDA presentation>			
10:20	10:55	The Use of Rapid Microbiological Methods (RMM) for Sterility Testing in ATMPs Manufacturing	Yasuhito Ikematsu Japan PDA Pharmaceutical Society, Chair of Aseptic Product GMP Committee Associate Professor, Graduate
10:55	11:30	Considerations for Aseptic Cleaning Based on Quantification of Residual Materials in Grade A Areas of ATMPs Manufacturing	Atsushi Kaneishi Japan PDA Pharmaceutical Society, Aseptic Product GMP Committee ROHTO Pharmaceutical Co., Ltd. Regenerative Medicine Research Planning Division
11:30	12:30	Lunch	
Session 5 <Facility design & CCS>			
12:30	13:05	A training on the Facility Design for ATMPs	Richard Denk Senior Consultant Aseptic Processing & Containment SKAN,
13:05	13:40	Set-up of a Contamination Control Strategy using the Hazard Analysis Critical Control Point (HACCP) methodology	Dr. Ruben van der Galien GE Healthcare,
Session 6 <Issues surrounding containers>			
13:40	14:15	The Critical Role of Container Closure Integrity in Cell & Gene Therapy and Biologic Packaging	Mr. Noba Ebaid afeguarding Pharmaceuticals PTI
14:15	14:50	From Factory to Patient: Packaging and Transport of Regenerative Medical Products	Takahiro Ogasawara Director of Product Development and Strategic Planning Office Japan Tissue Engineering Co., Ltd. (J-TEC)
14:50	15:20	Coffee Break	
15:20	16:10	Special Lecture Aligned Control Strategy Proportions and Staging Opportunities — Concept and Execution Roadmap for an Enhanced and	Stephan O. Krause, PhD Executive Director Analytical Strategy, BMS Cell Therapies
16:10	17:00	Special Lecture Development of smart cell manufacturing based on the QbD approach	Professor Masahiro Kino-oka Graduate School of Engineering, at The University of OSAKA
17:00	17:10	Summary & Closing remarks	Richard Denk