PDA Cell and Gene Pharmaceutical Products Conference 2025

Agenda

Tuesday, 18 November

Japan Standard Time Standard Time (UTC +9:00)

09:30 – 10:00	**Registration**	
10:00 – 10:15	**Opening Session**	
	10:00 – 10:15	**Opening Remarks** • **Shingo Sakurai** , Professor, *Tokyo University of Science, Laboratory of Pharmaceutical Quality Design and GMP*
10:15 – 11:25	**Current and Future Regulations (Part 1)**	
	10:15 – 10:50	**Current situation regarding regenerative medicine products: from the perspective of the Pharmaceuticals and Medical Devices Act** • **Yumiko Nomura** , Director of the 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	**Lunch**	
	11:35 – 11:50	**Körber Demo Session- Introduction and Future Outlook of Electronic Records in Regenerative Medicine Facilities** • **Nanami Taniguchi** , MES Consultant, *Körber Japan K.K. Pharma Software Division*
12:25 – 14:25	**Current and Future Regulations (Part 2)**	
	12:25 – 13:15	**Draft Revision of the Japanese Standards for Biological Raw Materials** • **Yoji Sato Ph.D.**, Deputy Director General, *National Institute of Health Sciences, Kanagawa, Japan*
	13:15 – 13:50	**An Overview of the Advanced Regenerative Medicine Regulation and Industry in Korea** • **So-Ra Park M.D., Ph.D.**, President & Founder, Regenerative Medicine Acceleration Foundation, *Professor, College of Medicine, Inha University*
	13:50 – 14:25	**Taiwan ATMP ecosystem and enabling CDMO** • **David Y.H. Chang, Ph.D.** , CEO, *Taiwan Bio-Manufacturing Corporation (TBMC)*
14:25 – 15:10	**Coffee Break**	
	Initiatives related to ATMP at PDA Headquarters	

15:10 – 16:55	15:10 – 15:45	**PDA Headquarters' Initiatives Regarding ATMP** • **Friedrich von Wintzingerode PhD**, Director, Microbiology and QC Individualized and Cell Therapy, *Genentech, a Member of the Roche Group*
	15:45 – 16:20	**Points to Consider(PtC) No. 11: Development, Classification, Manufacture, Control, and Testing of Plasmids and Vectors Used in ATMP Production** • **Darius Pillsbury** , Senior Consultant, *ValSource, Inc.*
	16:20 – 15:55	**Introduction to Points to Consider Regarding ATMP Raw Material Management** • **Takehiro Okumura Ph.D.**, General Manager, Alloy Therapeutics Japan, *Head of Quality, Alloy Cell Therapies*
17:00 – 19:00	**Social Gathering**	

Wednesday, 19 November

Japan Standard Time Standard Time (UTC +9:00)

08:30 – 09:00	**Registration**	
09:00 – 10:10	**Product Development (Part 1)**	
	09:00 – 09:35	**Development of Regenerative Medicine Product "Akuugo"** • **Kazumi Sawaguchi** , Head of Quality Assurance and Regulatory Affairs Division, *SANBIO*
	09:35 – 10:10	**Development and Post-marketing Issues of Japan's First Allogeneic Regenerative Medicine Product "TEMCELL ® HS Injection** • **Kiwamu Imagawa** , , *JCR Pharmaceuticals Co., Ltd. / AlliedCel Corporation*
10:10 – 10:20	**Break**	
10:20 – 11:30	**Product Development (Part 2)**	
	10:20 – 10:55	**The Use of Rapid Microbiological Methods (RMM) for Sterility Testing in ATMPs Manufacturing** • **Yasuhito Ikematsu** , Associate Professor, Graduate School of Engineering at The University of Osaka, *Chair of Aseptic Product GMP Committee, Japan PDA Pharmaceutical Society*
	10:55 – 11:30	**Considerations for Aseptic Cleaning Based on Visualization of Residual Stuff in Grade A Areas of ATMPs Manufacturing** • **Atsushi Kaneseki** , , *ROHTO Pharmaceutical Co., Ltd., Regenerative Medicine Research Planning Division / Japan PDA Pharmaceutical Society, Aseptic Product GMP Committee*
11:30 – 12:30	**Lunch**	
12:30 – 13:40	**Facility design & CCS**	
	12:30 – 13:05	**A training on the Facility Design for ATMPs for inspector** • **Richard Denk** , Senior Consultant Aseptic Processing, *SKAN AG*
	13:05 – 13:40	**Setup of a Contamination Control Strategy for ATMPs using the Hazard Analysis Critical Control Point (HACCP) Methodology** • **Ruben van der Galiën Dr.**, Qualified Person | Quality Assurance Professional | Pharmacist, *GE Healthcare*

13:40 – 14:50	**Issues Surrounding Containers (Part 1)**	
	13:40 – 14:15	**The Critical Role of Container Closure Integrity in Cell & Gene Therapy (CGT) and Biologic Packaging** • **Noba Ebaid** , Director of Sales, Americas & Asia-Pacific, *PTI – Packaging Technologies & Inspection*
	14:15 – 14:50	**Until it reaches the patient: The reality of containers, packaging, and transportation of regenerative medicine products** • **Takahiro Ogasawara** , Director of Product Development, *Japan Tissue Engineering Co., Ltd. (J-TEC)*
14:50 – 15:20	**Coffee Break**	
15:20 – 17:00	**Issues Surrounding Containers (Part 2)**	
	15:20 – 16:10	**Aligned Control Strategy Proportions and Staging Opportunities—Concept and Execution Roadmap for an Enhanced and Integrated Analytical Control Strategy for Autologous Cell Therapies** • **Stephan O. Krause Ph.D.**, Executive Director Analytical Strategy, *BMS Cell Therapies*
	16:10 – 17:00	**Development of smart cell manufacturing based on the QbD approach** • **Masahiro Kino-oka** , Professor, *Department of Biotechnology, Graduate School of Engineering, Osaka University & Research Base for Cell Manufacutrability, Graduate School of Engineering, Osaka University*
17:00 – 17:10	**Summary & Closing Remarks** **Richard Denk** , Senior Consultant Aseptic Processing, *SKAN AG*	