

PDA Cell & Gene Pharmaceutical Products Conference(PDA 細胞及び遺伝子医薬討論会)
 Date : from July 10th to July 11th
 Venue : Ochanomizu Solacity Conference Hall

Day 1 July 10th

time	title		Presenter	Affiliation	Moderator
9:00 ~ 10:00	reception				
10:00 ~ 10:15	Opening Remarks		Opening Remarks	Yoji Sato	NIHS Izumi Saitoh (Alba Aqua)
10:15 ~ 16:50	Session 1	Regulations and surrounding situations			
10:15 ~ 11:05	Presentation 1	Invited lecture	Advanced Analytical Control Strategies for Autologous Cell Therapies and current PDA ATMP Advisory Board Working Group Initiatives (TR 56-2 Annex 2 for ATMPs, ANS-007, RM Qualification, and other current initiatives)	Stephan Kraus	Executive Director, Analytical Science and Technology, Global CT Quality at Bristol Myers Squibb Shirokizawa Osamu (Life Scientia Ltd.)
11:05 ~ 11:55	Presentation 2	keynote lecture	未定	During negotiations	FDA Shirokizawa Osamu
11:55 ~ 12:40	Lunch	Lunch (bento box) will be provided.			
12:40 ~ 13:15	Presentation 3	keynote lecture	Regarding safety measures related to regenerative medicine products	Yumiko Nomura	Director, Pharmaceutical Safety Division, Pharmaceutical Department, Ministry of Health, Labor and Welfare Sakurai Shingou (Tokyo University of Science)
13:15 ~ 13:50	Presentation 4	Invited lecture	Points to consider for reviewing the quality of Cellular and Tissue-based Products	Atsushi Nishikawa	Pharmaceuticals and Medical Devices Agency, Office of Cellular and Tissue-based Products Sakurai Shingou
13:50 ~ 14:35	Coffee Break	Please visit the exhibition.Drinks will be provided.			
14:35 ~ 15:10	Presentation 5	Invited lecture	Promoting manufacturing infrastructure for regenerative/cell therapy and gene therapy	Hirokazu Shimoda	Ministry of Economy, Trade and Industry Commerce and Service Industry Policy Group, Head of Bio-Industry Division Yoji Sato(NIHS)
15:10 ~ 16:00	Presentation 6		Comparability Considerations for Cellular and Gene Therapy Products	Andrew Chang, Ph.D.	Vice President, Quality and Regulatory Compliance, Regulatory Policy and Intelligence, Global Regulatory Affairs, Novo Nordisk; Co-Chair BIO CGT Manufacturing Task Force Yoji Sato
16:00 ~ 16:50	Presentation 7		How To Be Inspection Ready for CGT Products : An End User Perspective and Case Study	Peter Qiu	EXTERNAL ADVOCACY LEAD, APAC AT ROCHE GENENTECH Yoji Sato
17:00 ~ 19:00	Social gathering (buffet)				

Day 2 July 11th

time			title	Presenter	Affiliation	Moderator
8:30 ~ 9:00	reception					
9:00 ~ 17:20	Session 2	Manufacturing				
9:00 ~ 9:50	Presentation 8	Invited lecture 3	Towards industrialisation of iPSC-derived allogeneic cell therapy	Márcia Mata, PhD	Associate Lead Scientist – Technology & Process Innovation - Cell and Gene Therapy Catapult	Yasuto Ikematsu
9:50 ~ 10:40	Presentation 9	Special lecture	My experience and next stage of myocardial regenerative medicine	Yoshiki Sawa, M.D., Ph.D.	Specially Appointed Professor, Division of Health Scienc Osaka University Graduate School of Medicine Director, Osaka Police Hospital	Yasuto Ikematsu (Osaka University)
10:40 ~ 10:50	Rest					
10:50 ~ 11:40	Presentation 10		Points to Consider for the Manufacturing of Cell and Gene Therapies, EU Annex 1, PIC/s Annex 2A incl. Bio-Safety requirements and Automation with Robotic.	Richard Denk	SKAN, Senior Consultant Aseptic Processing & Containment	Yasuto Ikematsu
11:40 ~ 12:30	Lunch	Lunch (bento box) will be provided.				
12:30 ~ 13:20	Presentation 11		Advanced practice initiatives of PIC/S GMP Annex 1 and 2A in Contamination Control Strategies (CCS) development.	Yasuto Ikematsu	Japan PDA Pharmaceutical Society, Chair of Sterile Products GMP Committee	Kino-oka Masahiro (Osaka University)
13:20 ~ 14:10	Presentation 12		When science meets industry: Towards fully automated CAR-T cell production - from lab scale applications to integrated commercial platforms	Kai Janning, M. Sc	Head of Business Development »Life Sciences Engineering«	Kino-oka Masahiro
14:10 ~ 15:00	Presentation 13		未定	Yukio Mori	J-TEC	Kino-oka Masahiro
15:00 ~ 15:40	Coffee Break	Please visit the exhibition. Drinks will be provided.				
15:40 ~ 16:30	Presentation 14		未定	Coordinating speakers and presentation topics	TAKARA BIO	Richard Denk (SKAN)
16:30 ~ 17:20	Presentation 15	Invited lecture 4	Concept of QbD approach in cell manufacturing and initiative toward process stabilization	Masahiro Kino-oka	Department of Biotechnology, Graduate School of Engineering, Osaka University	Richard Denk
17:20 ~ 17:30	Closing remarks		Summary & Closing remarks	Richard Denk	SKAN AG, PDA ATMP Advisory Board	Izumi Saitoh

We rent out simultaneous interpretation receivers.

Please return it every day