



2023 PDA Cell & Gene Pharmaceutical Products Conference

*The Present and Future of Manufacturing &
Quality of Cell-based Products*

12-13 July 2023 | Tokyo, Japan

Academic Partner :

一般社団法人日本再生医療学会

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Exhibitor:



PDA Cell & Gene Pharmaceutical Products Conference

2023-07-12

Time	Title	Speaker
9:30	Reception	
10:00	Opening declaration	Yoji Sato (NIHS Division Head of Division Of Cell-Based Therapeutic Products)
10:15	Opening Remarks	Glenn Wright (PDA President)
11:00	Key note lecture 1 Achieving Consistent Scalable Low-cost Production of High-Quality Living Therapeutic Cells.	Sean Palecek (University of Wisconsin, Professor)
12:00	Key note lecture 2 Current Status, Issues, and Direction of regenerative medicine products in Japan	Tomonori Nakayama (MHLW Division Head of Medical Device Evaluation Division)
12:30	Lunch	
13:30	Session 1 sterility	Moderator : Richard Denk (SKAN) /Yasuhiro Ikematsu (OSAKA UNIV.)
13:30	Presentation 1 Efforts of the PDA Pharmaceutical Society of Japan for practical use, dissemination, and development of rapid microbial testing methods	Mitsuo Mori (Kyowa Kirin Co., Ltd.)
15:00	Coffee Break	
15:45	Presentation 2 Contamination Control Strategy and Rapid Microbiological Methods in PIC/S GMP Annex 1 and Annex 2A	Yasuhiro Ikematsu (Specially Appointed Associate Professor, Graduate School of Engineering, Osaka University)
16:30	Presentation 3 Strategies and Examples for Ensuring Sterility of Cell-Processed Products	Tetsuya Karino (Sumitomo Pharma Co.,Ltd.)
17:15	Panel Discussion	
17:40-19:20	Social gathering (buffet)	

2023-07-13

Time	Title	Speaker
8:30	Reception	
9:00	Key note lecture 3 PDA Points to Consider for the Engineering and Manufacturing of Cell & Gene "ATMPs"	Richard Denk (SKAN Consultant Aseptic Processing & Containment)
9:50	Session 2 process	Moderator : Masahiro Kino-oka (Osaka Univ.)
9:50	Presentation 4 The Role of Virus Filtration in Achieving Virus Safety of Cell and Gene Therapy Products	Tomoko Hongo (Asahi Kasei Medical)
10:35	Presentation 5 Production and quality control of clinical-grade iPSCs and differentiated cells using an automated closed culture system.	Masayoshi Tsukahara (Research and Development Center, CiRA Foundation)
11:20	Presentation 6 Introduction and Process & Quality design for Alofisel Manufacturing Facility in Japan	Seitaro Mizukami (Takeda Pharmaceutical Industry)
12:05	Presentation 7 Lessons learned from clinic to commercialization for C> product	Sang Yoon (Samsung Biologics Senior Director of Quality)
12:50	Panel Discussion	
13:05	Lunch	
13:50	Session 3 quality	Moderator : Shingo Sakurai (Tokyo University of Science)
13:50	Presentation 8 What does the ICHQ5A revision mean for your cell & gene therapy product?	Alison Armstrong (Senior Director And Global Head Of The Technical And Scientific Solutions At Merck)
14:30	Presentation 9 Regenerative Medicine Product Quality Review and Issues	Akiyoshi Kunieda (PMDA Office of Cell and Tissue-based Products)
15:10	Coffee Break	
15:40	Presentation 10 PMDA's GMP/GCTP survey and risk communication activities	Kazuji Omori (PMDA Office Of Manufacturing Quality for Drugs)
16:20	Presentation 11 CQA Mining: A systematic approach for identifying CQAs of cell therapy products	Yoji Sato, Ph.D. (Head, Division of Drugs/Division of Cell-Based Therapeutic Products, National Institute of Health Sciences)
17:00	Panel Discussion	
17:15	Invited Lecture Challenging of development for a stable process based on cell manufacturability	Masahiro Kino-oka (Professor BioProcess Systems Engineering Lab., Dept.Biotech., Grad. Sch. Eng., Osaka Univ.)
18:00	Summary & Closing remarks	Richard Denk (SKAN Consultant Aseptic Processing & Containment)