



# 2023 PDA Cell & Gene Pharmaceutical Products Conference

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

**12-13 July 2023 | Tokyo, Japan**

Sponser

**MERCK**



**PDA Cell & Gene Pharmaceutical Products Conference**

**2023-07-12**

<b>Time</b>	<b>Title</b>	<b>Speaker</b>
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	under negotiation (NSF Engineering Research Center for Cell Manufacturing Technologies)
12:00	Key note lecture 2	Tomonori Nakayama (MHLW Division Head of Medical Device Evaluation Division)
12:30	Lunch	
13:30	Session 1 sterility	Moderator : Richard Denk (SKAN) / Yasuhito Ikematsu (OSAKA UNIV.)
13:30	Presentation 1	under adjustment
14:15	Presentation 2	under adjustment
15:00	Coffee Break	
15:45	Presentation 3	Mitsuo Mori (Kyowa Kirin Co., Ltd.)
16:30	Presentation 4	Tetsuya Karino (Sumitomo Pharma Co.,Ltd.)
17:15	Panel Discussion	
17:40-19:20	Social gathering (buffet)	

**2023-07-13**

<b>Time</b>	<b>Title</b>	<b>Speaker</b>
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 5 The Role of Virus Filtration in Achieving Virus Safety of Cell and Gene Therapy Products	Tomoko Hongo (Asahi Kasei Medical)
10:35	Presentation 6 Production and quality control of clinical-grade iPSCs and differentiated cells using an automated closed culture system.	Masayoshi Tsukahara (Center for iPS Cell Research and Application, Kyoto University.)
11:20	Presentation 7 Introduction and Process & Quality design for Alofisel Manufacturing Facility in Japan	Seitaro Mizukami (Takeda Pharmaceutical Industry)
12:05	Presentation 8 Lessons learned from clinic to commercialization for C&GT 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 9 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 10	Speakers are under consideration (PMDA Office of Cell and Tissue-based Products)
15:10	Coffee Break	
15:40	Presentation 11	Speakers are under consideration (PMDA Office Of Manufacturing Quality for Drugs)
16:20	Presentation 12	Yoji Sato (NIHS Division Head of Division Of Cell-Based Therapeutic Products)
17:00	Panel Discussion	
17:15	Invited Lecture	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)