

Agenda for APACRM 2024 (7th APACRM)

Brief Overview of APACRM 2024

Date of the Meeting: Thursday, April 25th, 2024

Venue (or Zoom): TOKYO MIDTOWN YAESU CONFERENCE (Please note the change in venue)

<https://www.yaesu.tokyo-midtown.com/en/conference>

Time (JST)	Duration	Session	Chair/Speaker/Panelist
13:00-13:03	3 min	Opening remarks	Yoshitsugu Shitaka, FIRM
13:03-13:10	7 min	Introduction	Masayuki (Max) Nomura, FIRM
13:10-14:10	Update on Regenerative Medicine from each Participating Industrial Association		
	60 min	10-min presentations from each country/region (Pre-recorded) * on site presentation	Takayuki Nakano, FIRM (Japan)
			Eugene, J. WANG, CMBA (China)
			Bryan Choi, CARM & RMAF (Korea)
			Pawan Kumar Gupta, ABLE (India)
			Chia-Ning Shen, BPIPO (Taiwan)
Srinivasan N Kellathur, SAPI (Singapore)*			
14:10-14:40	Educational Lecture		
	30 min	Points to Consider for Cellular Therapy CMC toward New Drug Application "NDA"	Yukio Mori, FIRM/J-TEC
14:40-15:10	Topics for future activities		
	30 min	Considerations for Conducting Clinical Trials of Regenerative Medicinal Products	Shigeaki Hayashi, FIRM/J-TEC
15:10-15:20	10 min	Break	
15:20-16:40 (80 min)	Points to Consider for Regulations on Marketing Authorization Application (MAA) for AAV-based Gene Therapies and CAR-T Products		
	10 min	Background and Objectives	Masaaki Miyano, FIRM/Chugai
	35 min	Panel Discussion 1: Regulatory review system	Panelists: 6 country/region regulators: TBD Eugene, J. WANG, CMBA/Help Tx Srinivasan N Kellathur, SAPI/Roche Moderator: Hirokuni Mizoguchi, FIRM/Astellas Ruriko Shinozaki, FIRM/Astellas
		<ul style="list-style-type: none"> Requirement of clinical data ERA review at BLA/MAA Alliance/reference country 	
35 min	Panel Discussion 2: CMC/GMP topics	Panelists: Same with panel discussion 1 Moderator: Masaki Fujii, FIRM/Mitsui-soko Masaaki Miyano, FIRM/Chugai	
	<ul style="list-style-type: none"> Out of specification In-country testing 		
16:40-17:10	Non-clinical data package for AAV-based Gene Therapies		
	30 min	Presentation and Discussion	Yusuke Kagawa, FIRM/Novartis Aki Kito, FIRM/Chugai ALL
17:10-17:55	Compilation of Case Studies on Cell and Gene Technology provided to the Patients as Medical Care or Medical Practice without Market Authorization		
	45 min	Presentation and Discussion	Kunihiko Suzuki, FIRM/MEDINET James Chieh-liang Lin, MEDIGEN ALL
17:55-18:00	5 min	Closing	Ken-ichiro Hata, FIRM
18:30-20:00	<Reception> Invite all in-person attendants		

Abbreviations: ABLE, Association of Biotechnology Led Enterprises in India; BPIPO, Biotechnology and Pharmaceutical Industries Promotion Office in Taiwan; CARM, Council for Advanced Regenerative Medicine in Korea; CMBA, China Medical Biotech Association in China; RMAF, Regenerative Medicine Acceleration Foundation in Korea; SAPI, Singapore Association of Pharmaceuticals Industries in Singapore.