DIA KoBIA Korea Biomedicine Industry Association RMAF 재생의료진흥재단 REGENERATIVE MEDICINE ACCELERATION FOUNDATION

Cell and Gene Therapy Summit

Pioneering Precision
- Cell and Gene Therapy Development and Innovation

27 February (Fri), 2026
Newilhan Memorial Hall, Severance Hospital, Seoul, Korea

Program Overview

The DIA Cell and Gene Therapy Summit — "Pioneering Precision: Cell and Gene Therapy Development and Innovation", co-hosted by DIA, RMAF, and KoBIA, will bring together Korea's leading scientific, regulatory, and industry stakeholders alongside global experts to discuss how precision medicine is shaping the future of cell and gene therapy development.

As a rapidly emerging contributor to global innovation, Korea offers world-class research capabilities, advanced clinical infrastructure, and strong policy support for biopharmaceutical development. This Summit will serve as a collaborative platform to explore strategies for accelerating clinical translation, advancing regulatory science, and expanding patient access to innovative therapies through close collaboration across science, regulation, and industry.

Focus and Discussion

This summit focuses on the evolving global regulatory and development landscape for cell and gene therapies, with perspectives from major health authorities including the FDA, EMA, NMPA, PMDA, and MFDS. Discussions will examine regulatory frameworks, approval pathways, and harmonization trends, alongside real-world case studies spanning CAR-T, gene editing, AAV gene therapies, and regenerative medicine. The program also explores clinical strategy, manufacturing comparability, and the transition from research to approval, while highlighting how patient data from clinical trials and real-world use can be leveraged to accelerate innovation and inform regulatory decision-making.

Who Should Attend

This Summit welcomes professionals from government agencies, academic institutions, hospitals, and biopharmaceutical companies engaged in the development, review , and regulation of cell and gene therapies. It will be particularly valuable for those working in regulatory affairs, clinical development, CMC, quality assurance, and translational science who wish to strengthen Korea's role in global CGT innovation and collaboration.

Program Chair

Yil-Seob Lee, MD, PhD
CHA University

Program Committee

Youngju Choi, PhD
National Institute of Food and Drug Safety Evaluation, Ministry of Food & Drug Safety
Esther Bahng, MSc
AstraZeneca Korea
In-sook Park, PhD
Korea Regulatory Science Center
So Ra Park, MD, PhD
Regenerative Medicine Acceleration Foundation
Jung Tae Park, PhD
Korea Biomedicine Industry Association(KoBIA)
Meehyun Jung
CTX, Inc.
MinYoung Kim, MD, PhD
CHA University School of Medicine
Young Joo Park, MPH, PhD
DIA Korea, Singapore and SEA

Program Facilitator

Jeongmin Choi
Korea Biomedicine Industry Association(KoBIA)

Supported by

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AGENDA | 27 February 2026 | ALL TIMINGS IN KST

The title and speaker(s) are subject to change.

9.00 – 9.10 am	**Opening Remarks**
	Young Joo Park, MPH, PhD, Vice President, Korea, Singapore, and SEA, DIA
9.10 – 9.50 am	**Plenary Session**
Session Chairs	**Yil-Seob Lee, MD, PhD**, CHA University
9.10 – 9.30 am	Pioneering Precision: Advancing Cell and Gene Therapy Through Science, Regulation, and Collaboration
	Kyung-Suk Kim, MD, PhD, Executive Advisor, CORESTEMCHEMON, Inc.
9.30 – 9.50 am	Global overview of cell and gene therapy (CGT) development, including key challenges and strategic considerations from a global perspective.
	Maria Vassileva, PhD, Chief Science and Regulatory Officer, DIA Global.
9.50 am – 12.20 pm	**Session 1** **Regulatory Overview of Cell and Gene Therapy Field**
	Session 1 will provide a comprehensive overview of the global regulatory landscape for cell and gene therapies development, featuring key updates and insights from major health authorities including the FDA perspective (U.S.), EMA (Europe), NMPA (China), PMDA (Japan), and MFDS (Korea). Representatives from these agencies will present the latest developments in regulatory frameworks, approval pathways, and guidance documents related to advanced therapies. The session aims to highlight harmonization efforts and evolving expectations across regions, offering participants a clearer understanding of how regulatory bodies are addressing the scientific and manufacturing complexities of cell and gene therapies. This discussion will lay the groundwork for subsequent sessions focusing on development, quality, and clinical perspectives.
Session Chairs	**Youngju Choi, PhD** Director General NIFDS, MFDS **In-sook Park, PhD** Director General KRSC
9.50 – 10.10 am	Regulatory Overview of Cell and Gene Therapy Fiel: The evolving EU framework for ATMPs
	Caroline Pothet, Head of advanced therapies and haemato-oncology European Medicines Agency
10.10 – 10.30 am	FDA Updates on Cell and Gene Therapy
	Tamei Elliott, M.S. Director, Global Scientific Content, DIA Global.
10.30 - 10.50 am	Current Status of Regenerative Medical Products in Japan
	Yasuhiro Kishioka, PhD, Review Director, Office of Celluar and Tissue-based Products PMDA, Japan
10.50 – 11.10 am	China's Policy Introduction on Accelerating Clinical Research and Development of Cell and Gene Therapy Products
	Jianchao Gao, MD. Associate Researcher, Changping Laboratory
11.10 – 11.30 am	Regulatory Update on CGT Development in Korea
	So-Young Wang, Director, Cell and Gene Therapy Products Division, Biopharmaceuticals and Herbal Medicine Evaluation Department, NIFDS, MFDS
11.30 – 11.45 am	**Coffee Break and Network**
11.45 - 12.20 pm	**Panel Discussion**
	Caroline Pothet, EMA **Tamei Elliott,** DIA **Yasuhiro Kishioka,** PMDA **Jianchao Gao,** Changping Laboratory **So-Young Wang,** NIFDS, MFDS **Meehyun Jung**, CTX, Inc. **MinYoung Kim**, CHA University School of Medicine , **Jung Tae Park**, KoBIA

12.20 – 1.20 pm	**Lunch and Network / Lunch Symposium - Sponsored Presentation**
	[Luncheon Seminar] Precision Medicine in Action: AstraZeneca's Cell and Gene Therapy Portfolio and Patient-Centered Strategy **Benjamin Taylor, PhD,** Senior Director, Cell Therapy Biotechnologies, AstraZeneca
1.20 – 2.40 pm	**Session 2-1** **Sharing regulatory experience from approved/authorized products**
	This session will present case studies highlighting key regulatory experiences and development challenges in advanced therapy medicinal products (ATMPs). Topics will include recent progress in CAR-T and gene editing therapies, as well as emerging approaches for autoimmune diseases from both data-driven and clinical development perspective. Further, the session will explore the scientific and regulatory complexities of demonstrating manufacturing sites and process comparability during clinical development. The session will also highlight examples of transitioning from regenerative medicine clinical research to product approval. Through these cases, participants will gain a deeper understanding of global regulatory strategies and best practices shaping the ATMP landscape.
Session Chairs	**Jung Tae Park, PhD** Vice Chairman Korea Biomedicine Industry Association **Hye Ryun Esther Bahng, MSc** Director of Market Access and Regulatory Affairs Astrazeneca
1.20 – 1.40 pm	Overseas approved products: CAR-T therapies and other gene-editing authorized products
	Just Weemers, Director, Global Regulatory Leader/ Global Regulatory Affairs - Oncology J&J Innovative Medicine
1.40 – 2.00 pm	Lessons Learned From Initial Cell and Gene Therapy Approvals
	Lana Shiu, MD, Global Head of Regulatory Affairs, Kite Pharma (Gilead)
2.00 – 2.20 pm	Autoimmune Disease – New Frontier in Cell and Gene Therapy Development
	Erin Finot, MS, MBA, Vice President, IQVIA Biotech, Cell & Gene Therapy **Jessica Knight-Perry, MD, MSc**, Senior Medical Director, Cell & Gene Therapy Center of Excellence, IQVIA
2.20 - 2.40 pm	Product Comparability in Cell Therapy: Approach to Managing Multifactorial Changes
	Patty Sachamitr, Associate Director, Analytical Strategy and Execution, A&QC, BlueRock Therapeutics
2.40 - 3.00 pm	**Coffee Break and Network**
3.00 - 4.00 pm	**Session 2-2** **Translating Emerging Gene and Cell Platforms into Clinical Development**
	This session will share real-world insights from U.S. FDA–approved in vivo AAV gene therapies, focusing on how key regulatory challenges were addressed during clinical development and licensure. It will also introduce emerging strategies for developing gene-edited, hypoimmunogenic iPSC-derived dopaminergic cell therapies, highlighting their potential and the considerations required to achieve clinical trial approval in Korea. Together, the session aims to bridge global experience with domestic innovation strategies.
Session Chairs	**Meehyun Jung** Executive Director CTX, Inc. **MinYoung Kim, MD, PhD** Professor CHA University School of Medicine
3.00 - 3.20 pm	Medipost's Global Clinical Development Experience: Regulatory and Development Pathways in Japan and the United States
	Antonio Lee, PhD, Global President & Board Director, MEDIPOST Co., Ltd
3.20 - 3.40 pm	A innovative gene therapy for wet AMD
	Zhenhua Wu, PhD, Founder and CEO, Exegenesis Bio Inc
3:40 - 4:00 pm	Generation of Hypoimmunogenic iPSC-Based Dopaminergic Neuron Cells via Gene Editing for Cell Therapy in Parkinson's Disease
	Yu Kyeong Hwang, PhD, CEO, CTX, Inc

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4.00 - 5.00 pm

Session 3
Advancing a paradigm shift in CGT regulatory perspective

This session will explore various aspects of patient data obtained through clinical research, clinical trials, and real-world use. It will also discuss how such data can be leveraged as a reliable and valuable resource to accelerate the development of advanced CGT products. In addition to case-based insights, this session will feature an interactive panel discussion with speakers from across the event, enabling a deep and multi-perspective dialogue on best practices, challenges, and opportunities in leveraging patient data for innovation.

Session Chairs

So Ra Park, MD, PhD
President
Regenerative Medicine Acceleration Foundation,

Eui-Kyung Lee, PhD, BPharm
Professor,
School of Pharmacy, Sungkyunkwan University

4.00 – 5.00 pm	**Panel Discussion** Patient Voice-Patient Engagement in Regulatory Decision-Making in Korea Requirements for preliminary clinical data for FDA's RMAT designation and its quality consideration Case examples of conditional approvals in Japan based on clinical study data Initiatives undertaken by the Chinese government for the paradigm shift in CGT-related regulations in China and to benefit patients Current status and key issues of relevant Patient focus guideline in Korea A brief perspective on patient access as a physician The need for paradigm shifts moving forward
	Eui-Kyung Lee, Sungkyunkwan University **Maria Vassileva,** DIA Global **Yasuhiro Kishioka,** PMDA **Jianchao Gao,** Changping Laboratory **Kyeongsoon Kim**, Vice President, Dream CIS **Youngil Koh,** Professor, Seoul National University Hospital
5.00 pm -	**Closing & Networking Reception**

REGISTRATION FORM : Register online or forward to DIA Korea@DIAglobal.org

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REGISTRATION

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	Government	Early Bird (until 31 Jan, 2026)	☐ 150
		After 1 February, 2026	☐ 180
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