6th DIA Cell and Gene Therapy Products Symposium in Japan

"Mastering Regenerative Medicine in Clinical Practice: Solving Issues at the Industrial Stage"

December 13-14, 2021

Day 1: Commercialization of Regenerative Medicines: Reliable and Stable Manufacturing and Supporting Quality - Latest Technologies and Knowledge

Day 2: Making Full Use of Regenerative Medicines: Further Connection and Understanding between Industries and the Medical Field

Web Hosting (Zoom Webinar)

Since the implementation of the Regenerative Medicine Promotion Act in 2013, which aims to facilitate the rapid and practical application of these products in Japan, active discussions among international stakeholders have helped accelerate clinical development of regenerative medicines for intractable diseases in both domestic and overseas markets, and multiple products have been put into practical use as therapeutic drugs. At the same time, specific issues at each stage, from R&D to commercialization have been clearly identified. DIA Japan has organized the Cell and Gene Therapy Symposium since 2016 as a platform for sharing issues among industry, government, and academia personnel and related parties to jointly explore solutions through constructive discussions. Since 2018, this symposium has covered gene therapy products and, as it has continued to evolve, has expanded to two days to accommodate active discussions between the industry, government, and academic communities. The vision of the symposium has also grown in line with the needs of frontline healthcare professionals and has moved from the initial stage of "practical application," in which regenerative medicine products are delivered to patients in the clinical setting to the next stage of practical application. Our 2020 symposium focused on "industrialization" to ensure that better products are continuously and stably delivered to the medical field and patients.

For 2021, under the title "Regenerative medicines that can be mastered in the medical field," we have prepared the two-day agenda to share issues through open and positive discussions about actions that we can take right now, as knowledge and experiences are being accumulated in all stages, from R&D to manufacturing to use in the medical field.

In Session 1 of Day 1, experts will jointly introduce and discuss new essential technologies such as next-generation genome sequencing (NGS) for acquiring data related to viral safety, an essential requirement for the development and timely provision of cellular and tissue-based biotechnology-derived pharmaceuticals, as well as issues related to the construction of databases and cooperative systems required for their practical application. Session 2 will focus on biodistribution related to evaluating the quality and safety of regenerative medicines. the discussions will encompass the latest technical information and issues related to biodistribution research on cell-processing and gene therapy products, as well as case studies and the current status of regional regulatory harmonization.

On Day 2, the concept of equivalence/homogeneity evaluation, a critical component of building efficient and stable manufacturing strategies and systems for cellular- and tissue-based products will be discussed in Session 3. Speakers with experience in the development of gene therapy products will share the issues that they have faced and how they dealt with them in case studies. Session 4 will address various distribution issues anticipated in the overall supply chain of products based on valuable company experiences in situations requiring a more advanced and complicated supply system in line with the characteristics of regenerative medicine products.

Session 5 will discuss the status of corporate requests for cooperation between industries and medical represented by the Cartagena Type 1 Use Regulations as well as challenges arising on the medical setting side. The discussion will deepen the understanding of both stakeholders and focus on exploring solutions to issues that may arise in medical settings to which a wide variety of regenerative medicine products will soon be entrusted.

This Symposium will continue to feature key opinion leaders (KOLs) to deliver keynote lectures. In 2021, Dr. Toshiyoshi Fujiwara (Okayama University) will discuss practical application of oncolytic virus research in the context of gene therapy in the oncology field. Dr. Hideyuki Okano (Keio University) will provide valuable updates on the latest iPS cell research and its application to central nervous system disease treatments.Dr. Shinichi Muramatsu (Jichi Medical School) will discuss the challenges of eradicating hereditary intractable diseases, including gene therapy for AADC deficiency.

The DIA Cell and Gene Therapy Symposium will continue to serve as a platform for continued discussions among the industry, academia, and government in Japan.It will continue to grow as a venue where participants can bring the latest issues in product development and industrialization back into their practical work, along with all the knowledge and insights required to solve these issues.

This symposium will take place in webinar format. Both a one-day pass and a registration package that combines Days 1 and 2 are available. These packages include a download service so that attendees can fully utilize the presentation materials, recorded sessions, and keynote lectures in their own home or work environment.

Virtual Exhibit Opportunities Available

For information, contact DIA Japan
Nihonbashi Life Science Building 6F,
2-3-11 Nihonbashihoncho, Chuo-ku, Tokyo 103-0023 Japan
Tel: +81.3.6214.0574 | Fax: +81.3.3278.1313
Email: Japan@DIAglobal.org

PROGRAM CHAIR
Yoji Sato, PhD
National Institute of Health Sciences (NIHS)

PROGRAM VICE-CHAIR
Yasuko Terao, PhD
Janssen Pharmaceutical K.K.

PROGRAM COMMITTEE
Teruyo Arato, PhD
Hokkaido University Hospital

Masaki Kasai, PhD
Pharmaceuticals and Medical Devices Agency (PMDA)

Satoru Hayata, MS
Sobi Japan

Sumimasa Nagai, MD, PhD
Kyoto University

Hiromi Okabe, PhD
Daiichi Sankyo Co., Ltd.

Kazunobu Oyama, PhD
Daiichi Sankyo Co., Ltd.

Masafumi Onodera, MD, PhD
National Center for Child Health and Development (NCCHD)

Hiroyuki Suda, MSc
KORTUC Inc.

Yoshie Tsurumaki
Novartis Pharma K.K.

PROGRAM ADVISORS
Akiko Ikeda
Janssen Pharmaceutical K.K.

OPERATION TEAM
Akiko Nishioka
Novartis Pharma K.K.

Simultaneous Translation Available

WHO SHOULD ATTEND?

Cell and gene therapy product development professionals in biopharmaceutical companies, medical devices companies, venture capital companies, regulatory agencies, or academia.

DIA volunteers, members, and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications, and educational materials, throughout the year, all around the world.

DIAglobal.org

DIA Japan
Nihonbashi Life Science Building 6F,
2-3-11 Nihonbashihoncho, Chuo-ku, Tokyo 103-0023 Japan
Tel: +81.3.6214.0574 Fax: +81.3.3278.1313 Email: Japan@DIAglobal.org

Drug Information Association
Global Center: Washington, DC | Americas | Europe, Middle East & Africa | China | Japan | India

10:00-10:15 WELCOME AND OPENING REMARKS

Hajime Saijo, PhD
Senior Vice President & Managing Director, DIA Japan

Yoji Sato, PhD
Program Chair
National Institute of Health Sciences (NIHS)

10:15-11:15 KEYNOTE ADDRESS 1

SESSION CHAIR

Daisaku Sato, PhD
Director, Compliance and Narcotics Division.
Ministry of Health, Labour and Welfare (MHLW)

Current Perspectives on Using High-throughput Sequencing (HTS) for Adventitious Virus Detection in Biologics

Arifa Khan, PhD
Senior Investigator in the Office of Vaccines Research and Review in the Center for Biologics Evaluation and Research (CBER), FDA

11:15-12:30 SESSION 1

Viral Safety – Current Status and Future Direction

SESSION CO-CHAIRS

Yoji Sato, PhD
Head, Division of Cell-Based Therapeutic Products, National Institute of Health Sciences (NIHS)

Kazunobu Oyama, PhD
Manager, CMC Regulatory Affairs, Daiichi Sankyo Co., Ltd.

Virus safety is extremely important for regenerative medical products, including viral vector products, as well as other biopharmaceuticals. In last year's symposium, we discussed the issues in the revision of ICH Q5A. In this session, we will review the technical and regulatory issues of viral safety assessment using next-generation sequencing (NGS), which is scheduled to be introduced in the revised Q5A. In addition, we will also share the activities of the Asian Regenerative Medicine Association Liaison Conference (APACRM), which has been conducting comparative study of Asian regulations for mesenchymal stromal cells as an example and has been discussing their viral safety evaluation. In the panel discussion, the speakers and Dr. Arifa Khan from the FDA will be invited for comprehensive discussions on the future direction of virus safety, based on the current status of the AVDTIG (Advanced Virus Detection Technologies Interest Group) and ICH Q5A(R2).

Possibility of NGS Alternative to in Vivo Test - Concept

Keisuke Yusa, PhD
Professor, Graduate School of Science, Technology and Innovation, KOBE university

Current Status of NGS Testing Implementation in US/EU and Regulatory Issues in Japan

Ryutaro Hirasawa, PhD
Bio-Virus Safety Committee, Parental Drug Association Japan Chapter (PDA Japan Chapter)

Eligibility of Mesenchymal Stem Cell as the Initiating Cell for the Production of Cell Therapy Products

Toshimitsu Tanaka, PhD
Regulatory harmonization committee (CMC regulatory affairs, regulatory affairs, Associate Director), Forum for Innovative Regenerative Medicine /Astellas Pharma Inc.

Panel Discussion

Session Speaker and
Arifa Khan, phD
Senior Investigator in the Office of Vaccines Research and Review in the Center for Biologics Evaluation and Research (CBER), FDA

12:30-13:30 LUNCH BREAK

13:30-14:15 KEYNOTE ADDRESS 2

SESSION CHAIR

Daisaku Sato, PhD
Director, Compliance and Narcotics Division.
Ministry of Health, Labour and Welfare (MHLW)

Multidisciplinary Oncolytic Virotherapy for Human Cancer

Toshiyoshi Fujiwara, MD, PhD
Professor,Graduate School of Medicine, Dentistry and Pharmaceutical Sciences,Okayama University

14:15-14:30 SHORT BREAK

14:30-16:10 SESSION 2

Biodistribution of Regenerative Medical Products

SESSION CO-CHAIRS

Yoji Sato, PhD
Head, Division of Cell-Based Therapeutic Products, National Institute of Health Sciences (NIHS)

Takashi Okada, MD, PhD
Director, Center for Gene and Cell Therapy, The institute of Medical Science, The University of Tokyo

Biodistribution (BD) of cell therapy products is one of important factors in view of tumorigenicity and/or the predictability of adverse effects, especially after systemic administration. With the evolving technology, tissue targeting of vector of gene therapy products dramatically progresses.
In this session, the audience can expect to hear the overview of the current technology for BD from the FIRM/AMED MEASURE group, the direction of ICH-S12, the art of sciences for designing BD vector engineering, and memory responses of the cell, which could be potential issues of BD.
This session also aims to encourage participants to consider future products development from the view of biodistribution.

Trend analysis and multi-site evaluation of non-clinical biodistribution studies for cell therapy products

Yoshiteru Kamiyama, PhD
Senior Director, Drug Metabolism & Pharmacokinetics Research
Analysis & Pharmacokinetics Research Labs, Astellas Pharma Inc.

ICH S12: Nonclinical Biodistribution COnsideration for Gene Therapy Products - Current Status

Masakazu Hirata, MD, PhD
Review Director, Office of New Drug V,
Pharmaceuticals and Medical Devices Agency (PMDA)

Generation of bespoke AAV for Safe Transduction

Takashi Okada, MD, PhD
Director, Center for Gene and Cell Therapy, The institute of Medical Science, The University of Tokyo

Memory Response of Gene Therapy Product – in View of Biodistribution –

Yuki Kagoya, MD, PhD
Chief, Division of Immune Response, Aichi Cancer Center Research Institute

Panel Discussion

All Session Speakers

16:10-16:25 COFFEE BREAK

16:25-17:10 KEYNOTE ADDRESS 3

SESSION CHAIR

Daisaku Sato, PhD
Director, Compliance and Narcotics Division.
Ministry of Health, Labour and Welfare (MHLW)

iPSCs-Based Regenerative Medicine and Drug Development

Hideyuki Okano, MD, PhD
Professor, Department of Physiology, Keio University School of Medicine

9:30-9:45 OPENING - DAY 2

SESSION CHAIR

Yasuko Terao, PhD
Director, ASPAC Lead, Global Government Grant Office (G3O), Janssen Research & Development, Janssen Pharmaceutical K.K.

Development Status and Issues of Gene Therapy Products
Masafumi Onodera, MD, PhD
Director, Gene & Cell Therapy Promotion Center, NCCHD

9:45-11:15 SESSION 3

Point to Consider on CMC Comparability Challenges Through the Development of the Gene Therapy Products

SESSION CO-CHAIRS

Kazunobu Oyama, PhD
Manager, CMC Regulatory Affairs, Daiichi Sankyo Co., Ltd.

Mika Yoshimatsu, MS
Manager, CMC Sciences Department, Janssen Pharmaceutical K.K.

During the development of the gene therapy products, CMC events such as process improvements or production site changes often happens. Comparability strategies addressing to these CMC concerning changes will be critical, particularly at the late phase development, not only for promoting clinical studies smoothly but also for the successful marketing authorization approval within the expected timeframe. In addition, science-based, and technical-based considerations are necessary for discussing the evaluation of comparability, especially in the development of new modality products. In this session, we will have speakers who will share their insights and experiences of comparability approaches and challenges in the global CMC development. The panel discussion will focus on general considerations, challenges, and current difficulties with applying the risk-based and science-based approach on the gene therapy product development.

Analytical Comparability Strategies for AAV Gene Therapy Products
Jaclyn Moxham, MS
Senior Director, Biotherapeutics GCMC,Pfizer, Inc.

Demonstrating Comparability if AAV Gene Therapy Products during Clinical Development : Managing the Link Between the Product and the Process
Niamh Kinsella, PhD
Associate Director, Global Regulatory CMC Early Development Gene Therapy Lead, .Biogen Idec Ltd.

Global Regulatory and Testing Trend of the Virus Vector Drugs
Alison Armstrong, PhD
Global Head of Field Technology Management, BioReliance, Merck

Panel Discussion
All Session Speakers
Atsushi Nishikawa, M.Sc
Office of Cellular and Tissue-based Products, Pharmaceuticals and Medical Devices Agency
Sadao Ozawa, Ph.D
Merck Ltd.

11:15-11:30 COFFEE BREAK

11:30-12:15 KEYNOTE ADDRESS 4

SESSION CHAIR

Masafumi Onodera, MD, PhD
Director, Gene & Cell Therapy Promotion Center, NCCHD

AAV Gene therapy for Parkinson Disease and AADC deficiency
Shinichi Muramatsu, MD, PhD
Professor, Open Innovation Center, Jichi Medical Univercity

12:15-13:15 LUNCH BREAK

13:15-14:55 SESSION 4

Issues and Initiatives in the Supply Chain of Regenerative Medical Products ~ for Further Promotion of the Industrialization ~

SESSION CO-CHAIRS

Teruyo Arato, PhD
Professor, Hokkaido University Hospital

Yoshie Tsurumaki, Rph
Senior External Relation Manager, Cell & Gene Franchise, Oncology Division, Novartis Pharma K.K.

The supply chain of regenerative medical products is sophisticated and complicated, and it is necessary to build a more reliable supply system according to the characteristics of each product. Consistent quality control is required in the process of raw material collection, manufacturing, shipping, and transportation. In addition, the realization of a stable supply is indispensable for further promotion of the industrialization of regenerative medical products, and many discussions have been held on the construction of a stable supply system for cell raw materials.
In this session, speakers from regulators, companies, academia, and medical institutions will share various issues and initiatives throughout the supply chain with examples, and in the panel discussion, discussions will be deepened on solutions to each issue.

Overview : The Issues Related to Supply Chain Management of Regenerative Medical Products
Masaki Kasai, PhD
Office of Cellular and Tissue-based Products, Deputy Review Director, Pharmaceuticals and Medical Devices Agency (PMDA)

Challenges for Autologous CAR-T Cell Journey Platform Establishment
Tokuhito Sumitani, MSc, RPh
Clinical Development Department II, Daiichi Sankyo Co., Ltd.

Establishment and Reality of the Supply Chain System for the Allogeneic Regenerative Medicine Product,TEMCEL®HS Injection
Kiwamu Imagawa, PhD
Director, Regenerative Medicine, Research Division, JCR Pharmaceuticals Co., Ltd.

To Establish the Stable Supply System of Perinatal Appendage-Derived Cells as a Source of Regenerative Medicine Products
Tokiko Nagamura, MD, PhD
Department of Cell Processing and Transfusion, IMSUT Hospital, The Institute of Medical Science, The University of Tokyo

Panel Discussion
All Session Speakers

14:55-15:10 COFFEE BREAK

15:10-15:50 EDUCATIONAL LECTURE

SESSION CHAIR

Teruhide Yamaguchi, PhD
Professor, Kanazawa-Instituite of Technology

GMO Procedures and Requirements for ATMPs in the EU
Stuart Beattie, PhD
Regulatory CMC Gene Therapy Clinical Lead, Biogen

15:50-17:20 SESSION 5

Actual Requirements of Cartagena Type Use 1 for Medical Institutions from Pharmaceutical Point of View

SESSION CO-CHAIRS

Daisaku Sato, PhD
Director, Compliance and Narcotics Division.
Ministry of Health, Labour and Welfare (MHLW)

Sumimasa Nagai, MD, PhD
Institute for Advancement of Clinical and Translational Science(iACT)
Kyoto University Hospital

The number of products developed for gene therapy has been increasing, and some products have been launched in Japan. On the other hand, the gap between companies and medical sites regarding the manuals on the use of gene therapy products has become apparent.
In this session, the actual situation will be grasped, and utilization in actual medical fields, feasibility, and future issues will be discussed. In particular, we will focus on the gap between the "Type 1 Use " specified for each product in the regulations and the" Manual for Site Requirements and Sites Prepared by Companies ", and we will discuss the appropriate countermeasures by sharing the actual situation and organizing the basic idea of the regulations.

A Fact-Finding Survey of Handing Gene Therapy Products Compliance with Type 1 Use Regulations of the Cartagena Law in Clinical Site
Masafumi Onodera, MD, PhD
Director, Gene & Cell Therapy Promotion Center, NCCHD

Panel Discussion
All Session Speakers and
Teruhide Yamaguchi, PhD
Professor, Kanazawa-Instituite of Technology
Masato Komuro, PhD
Manager, Regulatory Affairs, Novartis Pharma K.K.
Kyoko Yamada, MSc
Clinical Study Management, Chugai Pharmaceutical Co., Ltd.
Miyako Matsumizu
Phizer R&D

17:20-17:30 CLOSING REMARKS

Yasuko Terao, PhD
Program Vice-chair
Director, ASPAC Lead, Global Government Grant Office (G3O), Janssen Research & Development, Janssen Pharmaceutical K.K.

REGISTRATION FORM: Register online or forward to
DIA Japan, Nihonbashi Life Science Building 6F, 2-3-11 Nihonbashi-honcho, Chuo-ku, Tokyo 103-0023 Japan
tel +81-3-6214-0574 • fax +81-3-3278-1313

6th DIA Cell Therapy and Gene Therapy Products Symposium in Japan

Event #21313 • December 13-14, 2021 | Web Hosting (Zoom Webinar)

DIA will send participants a confirmation letter within 10 business days after receipt of their registration.

Registration Fees If DIA cannot verify your membership, you will be charged the nonmember fee. Registration fee includes refreshment breaks and reception (if applicable), and will be accepted by mail, fax, or online.

Join DIA now to save on future meetings and to enjoy the benefits of membership for a full year: www.DIAglobal.org/Membership

❑ I DO want to be a DIA member

❑ I DO NOT want to be a DIA member

			10% CONSUMPTION TAX INCLUDED		
			2 DAYS	DAY 1 ONLY	DAY 2 ONLY
MEMBER *	Industry	Early Bird (Until Nov. 29, 2021)	¥37,400 ❑	¥25,900 ❑	¥25,900 ❑
		On of After Nov.30, 2021	¥42,900 ❑	¥28,160 ❑	¥28,160 ❑
	Government, Non Profit, Academia, Medicals	Early Bird (Until Nov. 29, 2021)	¥19,800 ❑	¥11,800 ❑	¥11,800 ❑
		On of After Nov.30, 2021	¥22,000 ❑	¥13,200 ❑	¥13,200 ❑
NONMEMBER	Industry		¥62,150 ❑	¥35,860 ❑	¥35,860 ❑
	Government		¥41,250 ❑	¥23,100 ❑	¥23,100 ❑
	Non Profit, Academia, Medicals		¥35,200 ❑	¥19,250 ❑	¥19,250 ❑
MEMBERSHIP	Membership		¥22,000 ❑		
	2-Year Membership		¥39,600 ❑		
	Academia Membership (Academia, Medicals)*		¥15,180 ❑		
	2-year Academia Membership (Academia, Medicals)*		¥27,200 ❑		

Early Bird Deadline: November 19, 2020

* Including members of Forum for Innovative Regenerative Medicine (FIRM).

** To register for Academia Membership, please send this form to DIA Japan office by fax or e-mail.

Please check the applicable category:

❑ Academia ❑ Government ❑ Industry ❑ Medicals

❑ CSO (Contract research/service organization) ❑ Student (Call for registration information)

Last Name

First Name M.I.

Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Job Title

Company

Address (As required for postal delivery to your location)

City State Zip/Postal Country

email Required for confirmation

Phone Number Required Fax Number

DIA Terms and Conditions

CANCELLATION POLICY: On or before November 15, 2021

Administrative fee that will be withheld from refund amount:

Member or Nonmember = ¥20,000

Government/Academia/Nonprofit

(Member or Nonmember) = ¥10,000

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid.

Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

EVENT STREAM AND RECORDING

If you attend a DIA event, we make video and audio recordings of events (both face to face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click here. (https://www.DIAglobal.org/general/photography-policy)

PRIVACY STATEMENT

The personal information you request will be used for the purpose of sending conference information from DIA. In addition, in the web conference, we will use the information with the name of the company or organization and the name of everyone who participates, and it will be used for networking with participants, related parties, exhibiting companies for the period and about two weeks after the event. .. By submitting this application form, it is interpreted that you have consented to the above handling of personal information, but if you do not agree, please contact DIA Japan.

By signing below I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or online by clicking here. (https://www.diaglobal.org/General/Terms-and-Conditions?productIDs= 9276679)

Signature Date

PAYMENT OPTIONS

Register online at www.DIAglobal.org or check payment method.

❑ BANK TRANSFER:
You will recieve an invoce with bank information detail by email after registration completion.
All local and overseas charges incurred for the bank transfer must be borne by payer.

❑ CREDIT CARD (VISA, MASTERCARD OR JCB ONLY)

❑ VISA ❑ MC ❑ JCB Exp. (mm/yy)

Card No.

Cardholder Name

Signature

CONTACT INFORMATION
Contact the DIA Japan office in Tokyo for further information.
tel: +81.3.6214.0574 | fax: +81.3.3278.1313
email: Japan@DIAglobal.org
www.diajapan.org

DIA