7th DIA Cell and Gene Therapy Products Symposium in Japan

"Ten Years Progress of Cell and Gene Therapy Products – Leap forward with our initial passion"

December 15-16, 2022

Hybrid | KFC Hall http://www.tokyo-kfc.co.jp/access **& Virtual**

Since the legislative Regenerative Medicine Promotion Act in 2013, clinical development of many regenerative medical products for intractable diseases has accelerated and many such products are currently being used in clinical practice. This annual symposium has continuously discussed "practical aspects" such as the industrialization, practical use, and eventual mastery of regenerative medical products in clinical practice.

The year 2022 marks the "ten years since the legislation" milestone. This year's symposium, subtitled "Ten Years Progress of Cell and Gene Therapy Products – Leap forward with our initial passion," is intended to recall and reignite our original passion to "ensure that we deliver new solutions to patients" at the time of the law was issued, our aspirations to realize it, to look back on the progress of product development, and to prepare for a further leap forward.

In a special lecture, Dr. Daisaku Sato (Ministry of Health, Labour and Welfare), whose work was dedicated to enactment of the law, will discuss the philosophy and thought at the time it was enacted. In Session 1, key panelists from industry, government, and academia will review their accumulated achievements to discuss future development. Other sessions will discuss a viral safety assurance strategy based on revision of ICH-Q5A; a manufacturing control strategy utilizing the international standard; and introduce the latest nonclinical research topics based on different ways of thinking between cell and gene therapy products in nonclinical studies. Another session will feature presentations from physician who are heavy users of regenerative medical products.

Keynote lectures from thought leaders Dr. Yoshiki Sawa (Osaka Police Hospital) and Dr. Keiya Ozawa (Jichi Medical University) will review their initial passion, encourage passion from the audience, and set expectations for further advances in cell therapy and gene therapy products. In addition, Dr. Jacqueline Barry will share her valuable knowledge and experience in the educational lecture Strategy from searching new seeds to development.

Like previous years, our 7th DIA Cell and Gene Therapy Products Symposium in Japan will share issues among industry, government, and academia, and provide a forum for constructive discussions and solutions. This year presents a wider range of topics than ever across **two days you don't want to miss!!**

We plan to hold a hybrid meeting. Networking at the venue will resume. We look forward to this opportunity to expand our network with many people. In addition to a service for downloading presentation materials (as PDF files), we also plan to offer a service for distributing videotapes of each session and keynote speech for a limited time after the symposium.* We are confident that these will allow you to make full use of the symposium contents in accordance with your needs, and look forward to welcoming as many participants as possible this year.

*Please note that there may be restrictions on recording and sharing materials based on the content and nature of each session or lecture.

Expected contributors:

- Individuals involved in the development of regenerative medical products in pharmaceutical or medical device companies and related industries.
- Individuals involved in the development of regenerative medical products in venture companies or academic institutions.
- Individuals involved in regulatory submissions work for regenerative and related medical products.

Please Click here for COVID-19 Measures

Exhibit Opportunities Available

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Drug Information Association
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Simultaneous Translation Available

WHO SHOULD ATTEND?

Cell and gene therapy product development professionals in pharmaceutical companies, medical devices companies, venture 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

10:00-10:15 WELCOME AND OPENING REMARKS

Hotori Hasegawa
DIA Japan

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

10:15-10:45 SPECIAL LECTURE

SESSION CHAIR

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

Development of Regenerative Medical Product Regulations : Our Initial Passion and the Future

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

10:45-11:00 SHORT BREAK

11:00-12:50 SESSION 1

Looking Back on the Past Nine Years for a Further Leap Forward

SESSION CO-CHAIRS

Kiyoshi Okada, MD, PhD
Specially Appointed Associate Professor, Graduate School of Medicine, Osaka University

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

Year 2022 is the 10th year from the revision of the Safety assurance for regenerative medicine Law and the PMD Law in 2013. Over the past 9 years, the development of regenerative medical products has progressed, and new products are gradually coming to the market. Four products have been approved under the conditional approval system. In their development, various challenges, focusing on how development of these products is different from biological drug and medical device development, have been identified.

In this session, key panelists from industry, government, and academia will review these revisions and share their concerns about prior development, review and approval, related decisions made, and their prospects and hopes for the future.

What Should be Done for the Appropriate Operation of the Unique Legislative System for the Development of Regenerative Medical Products?

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

Japanese Gene Therapy in the Last 30 Years What changed and what did not change?

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

Industrialization of Regenerative Medicine: Past and Future Prospects

Kenichiro Hata, MD, PhD
President & CEO, Japan Tissue Engineering Co., Ltd.

Panel Discussion

All Session Speaker and

Yoshiki Sawa, MD, PhD
Hospital Director, Osaka Police Hospital

Yoshiaki Maruyama, PhD
Reveiw Director, Pharamaceutical and Medical Devices Agency (PMDA)

12:50-14:00 LUNCH BREAK

14:00-15:00 KEYNOTE ADDRESS 1

SESSION CHAIR

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

TBD

Yoshiki Sawa, MD, PhD
Hospital Director, Osaka Police Hospital

15:00-15:20 COFFEE BREAK

15:20-17:00 SESSION 2

Revision of ICH Q5A and Upcoming Challenges for Virus Safety Management of Gene and Cell Therapy Products

SESSION CO-CHAIRS

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

Ryutaro Hirasawa, PhD
CMC Regulatory Affairs, Manager, Daiichi Sankyo Co., Ltd.

Virus safety management is one of the essential issues in assuring the quality (quality assurance) of gene and cell therapy products. This annual symposium has previously discussed topics regarding the revision of the ICH Q5A guideline and virus safety assessment with new technologies, including upcoming challenges. This year, we will discuss an advanced approach for virus safety management in the context of the upcoming release of the ICH Q5A (R2) draft and review the basic concept of this guideline.

This session will feature experts with crosscutting experiences across different types of products, provide opportunity to discuss regulatory and technological challenges for future virus safety management.

Overview of ICH-Q5A(R2) and Basic Approach to Ensuring the Virus Safety of Gene and Cell Therapy Products

Akira Sakurai, PhD
Specialist, Pharmaceuticals and Medical Devices Agency (PMDA)

Global Trend in the Substitution of In vivo Testing / Antibody Production Testing by Molecular Methods

Alison Armstrong, PhD
Senior Director, Global Head of the Technical and Scientific Solutions, Merck

Practical Application of Virus Filtration for Gene Therapy Products

Tomoko Hongo-Hirasaki, PhD
Lead expert, Asahi Kasei Medical Co., Ltd.

Panel Discussion

All Session Speakers and

Yuko Kato-Mori, PhD
President & Director of Virus Study Department, ViSpot Inc.

17:00-17:10 SHORT BREAK

17:10-17:50 EDUCATIONAL LECTURE

SESSION CHAIR

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

Cell and Gene Therapy Catapult – Supporting Innovation

Jacqueline Barry, PhD
Cell and Gene Therapy Catapalt

17:50-18:00 SHORT BREAK

18:00-19:00 NETWORKING

9:00-10:50 SESSION 3

Manufacturing Management Strategy Utilizing International Standards

SESSION CO-CHAIRS

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

Ikuo Kawauchi, MS
International Standards Promotion Office, Intellectual Property Div.
FUFIFILM Holdings Corporation

International standards in the fields of regenerative medicine are developed and published mainly by ISO/TC 276 (Biotechnology). These standards can be classified into three categories: products and services of supporting industries, manufacturing, and analytical methods.

After a brief explanation of standards, this session will discuss the characteristics of standards related to supporting industries such as reagents and media, manufacturing equipment, and transportation; development of a "cell processing management standard" plan for consistent manufacturing; and overview the "testing and characterization of cellular therapeutic products," "cell counting," and "cell viability" for analytical methods standards. Panel discussion will examine how utilization of these standards, including expected effects and measures to facilitate utilization, contributes to manufacturing management.

International Standards Related to Products and Services of Supporting industries

Ikuo Kawauchi, MS
International Standards Promotion Office, Intellectual Property Div.
FUFIFILM Holdings Corporation

Standardization in Cell Processing Management

Ryuji Kato, PhD
Associate Professor, Tokai National Higher Education and Research System, Nagoya University

Testing and Characterization of Cellular Therapeutic Products

Yuzuru Ito, PhD
Professor, Faculty of Life and Environmental sciences, University of Tsukuba

Trends in international Standards for Cell Analysis including Cell Counting and Cell Viability

Masakazu Kadowaki, PhD
Director, Business Incubation, Sysmex Corporation

Panel Discussion

All Session Speakers

Shinichi Noda
Office of Cellular and Tissue-based Products, Deputy Review Director, Pharmaceuticals and Medical Devices Agency(PMDA)

10:50-11:10 COFFEE BREAK

11:10-12:50 SESSION 4

Tips and Pitfalls for Preparing Cell and Gene Therapy Product Non-Clinical Studies

SESSION CO-CHAIRS

Teruyo Arato, PhD
Professor, Hokkaido University Hospital

Hiroyuki Suda
VP, Clinical Strategy, KORTUC Inc.

Cell therapy and gene therapy products are treated as the same category in the regenerative medical products regulations in Japan. However, different approaches are required in designing non-clinical studies, since certain characteristics of cell therapy and gene therapy products are quite different.

This session will broadly cover non-clinical studies on regenerative medical products by examining the differences in regulatory requirements between these two modalities, with experts in each area sharing their approaches to current issues and hot topics.

TBD

Teruhide Yamaguchi, PhD
Professor, Kanazawa-Instituite of Technology

Industrialization of Cell Products for Stroke and Alzheimer's Disease Based on Mechanism of Action

Akihiko Taguchi, MD, PhD
Department of Regenerative Medicine Research, Institute of Biomedical Research and Innovation

Infrastructure Development for Nonclinical Safety Studies in Non-human Primates Aiming for the Clinical Application of Japan-made Cellular and Gene Therapy Products

Yozo Nakazawa, MD, PhD
Professor, Department of pediatrics, Shinshu University School of Medicine

Consideration on Nonclinical Studies of Gene Therapy Products from Industry

Takefumi Gemba, PhD
Executive Director, Clinical & Regulatory Strategy,
Labcorp Development Japan K. K.

14:55-15:10 LUNCH BREAK

15:10-15:50 KEYNOTE ADDRESS 2

SESSION CHAIR

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

R&D of Gene Therapy for 30 Years and Future Perspective

Keiya Ozawa, MD, PhD
Professor Emeritus and Visiting Professor, Jichi Medical University

15:50-17:30 SESSION 5

How to Deliver Cellular and Gene Therapy Products: Feedback from Medical Institutions

SESSION CO-CHAIRS

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

Hideki Mochizuki, MD
Graduate School of Medicine, Osaka University

As of July 2022, 16 cellular and tissue-based products have been launched across various modalities such as tissue-engineered products, cell-based products, ex vivo cell therapy products, and gene therapy products. But much effort is required to use these products in medical institutions, including preparation for and introduction to actual operation, actual operation, improving operations required to use and administer these products, and contrivances to improve their therapeutic effects.

In this session, physicians with real-word experience with using commercial cellular and tissue-based products will speak about their previous experiences, current situation, and proposals for future improvement. Panel discussion will examine requests to companies and regulatory authorities for clinical use.

Treatment of Patients with Extensive Burns Using the Cultured Epidermal Autografts

Takahiro Ueda, MD
Professor, Altitude Emergency and critical care medical center, Tottori University Hospital

Autologous Cultured Cartilage JACC®: 10 years of Clinical Application and the Future

Yuki Kato, MD
Chief, Sports Medicine Center, Kameda Medical Center

Clinical applications of Mesenchymal Stem Cell 'Now and Future'

Kentaro Fukushima, MD
Senior Lecturer, Department of Hematology and Oncology, Graduate School of Medicine, Osaka University

Lights and Shadows in CAR-T Cell Therapy - Expectation and Exhaustion of the Clinical Team

Yasuyuki Arai, MD, PhD
Senior Lecturer, Center for Research and Application of Cellular Therapy, Kyoto University Hospital

Using Zolgensma in the Real World

Yuko Shimizu-Motohashi, MD
Department of Child Neurology, National Center of Neurology and Psychiatry

Panel Discussion

All Session Speakers

17:30-17:45 CLOSING REMARKS

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

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Event #22313 • December 15-16, 2022 | Hybrid | KFC Hall (Virtual)

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NONMEMBER	Industry		¥86,460	❑
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****Revised from July 1, 2022*

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