DIA

Korea Regulatory Science Center

# 2023 KRSC-DIA Workshop

## Regulatory science for the development of innovative healthcare technologies after the COVID-19 pandemic

**Dec.5.2023. 09:00-17:15/Auditorium in central post office, Seoul, Korea ( 서울 중앙 우체국 10 층 대강당 )**

Ministry of Food and Drug Safety | ARICTT | KFDC (사)한국에프디시규제과학회 | KoBIA Korea Biomedicine Industry Association | KRPIA 한국글로벌의약산업협회 | KSCPT 대한임상약리학회 | KSPM The Korean Society of Pharmaceutical Medicine www.kspm.org | KPBMA 한국제약바이오협회

## Overview

Due to the COVID-19 pandemic, we around the world have experienced a period of chaos.
But we overcame the pandemic at a very rapid pace as much it feels like a long time ago.

For the past three years, we made the meaningful and remarkable results of technological development and innovations in the healthcare industry and also we learned how important to make it come quickly into our lives.

Regulatory science is an innovation technology in healthcare sector that contributes to humanity faster and safer works to propose regulatory standards based on scientific data and evidence.

Korea Regulatory Science Center and DIA organized this joint workshop with the title of "Regulatory science for the development of innovative healthcare technologies after the COVID-19 pandemic." We invited experts with extensive experience in domestic and foreign regulatory agencies, academia and industry, including the United States and Japan and other countries, to present the latest trends in regulatory science and healthcare innovations.

**Sessions are as follows:**

- **Session 1 :** Pathway for implementation of Regulatory Science and future perspective
- **Session 2 :** Regulatory environment of Real world evidence(RWE)/ Real World Data(RWD)
- **Session 3 :** Opportunities and Challenges for Decentralized Clinical Trials (DCTs) through the Lense of Regulatory Science
- **Session 4 :** Regulatory Science in the era of therapeutic transformation with cell & gene therapy.

Capacity of Attendees : 150 people

## Program Committee

**YilSeob Lee, MD, Ph.D.**
Professor, CHA University

**Insook Park, Ph.D.**
Director General/KRSC

**HaeSun Suh, Ph.D.**
Professor, KyungHee University

**SoHee Kim, Ph.D.**
Division Director, MFDS

**HeaYoung Cho, Ph.D.**
Professor, CHA University

**JoonWoo Bahn, MD. Ph.D.**
Professor, Director, Asan Medical Center

**JeeWon Joung, Ph.D.**
Director, MFDS

**JooYeon Han**
Associate Director, AstraZeneca

**HyangWon (Harriet) Min, MSc.**
Vice President, Johnson & Johnson

**SoJung Lee**
VP, Regulatory Affairs, Samsung Biologics

**Shogo Nakamori, MBA**
SVP & MD, DIA Global

**TaekYoung Kim, MBA**
Country Manager, Korea

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**The Drug Information Association, Inc.**
DIA Global Center: Washington, DC, USA | Basel, Switzerland | Beijing, China Horsham, PA, USA | Mumbai, India | Tokyo, Japan

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**DIAglobal.org**

**2023 KRSC-DIA Workshop:**
Regulatory science for the development of innovative healthcare technologies after the COVID-19 pandemic

## Agenda

| Time | Topics | Chair / Speaker |
|---|---|---|
| 8:30-9:00 | Registration | |
| 9:00-9:10 | Opening Remarks | InSook Park, Diector General, KRSC |
| 9:10-9:20 | Congratulation Remark | Shogo Nakamori, SVP & MD, DIA Global<br>YounJoo Park, Director General, NIFDS<br>YunHong Noh, Chairman, KPBMA |
| Session I | Pathway for implementation of Regulatory Science and Future Perspective | **Chair**<br>InSook Park,Director General,KRSC<br>SunHee Lee Prof. Ewha Womans University |
| **Time** | **Topics** | **Chair / Speaker** |
| 9:20-9:45 | How Effectively is PMDA Collaborating with Other Regulatory Agencies Like USFDA/EMA etc in Terms of Regulatory Science ? | Ogata Akiko,<br>Director PMDA JAPAN |
| 9:45-10:10 | How PMDA Communicate with Industries and Seeks New Solutions to New Technologies in the Used in Product Development | Mako Kawahara,<br>Technical Officer, PMDA JAPAN |
| 10:10-10:35 | MFDS's Strategic Plan for Advancing Regulatory Science and Status | JinHwi Kim, Director, MFDS KOREA |
| 10:35-11:00 | Panel discussion | All |
| Session II | Regulartory environment of Real world evidence(RWE)/Real World Data(RWD) | **Chair**<br>HaeSun Suh, Prof. Kyung Hee University<br>SoHee Kim, Division Director, MFDS KOREA |
| **Time** | **Topics** | **Chair / Speaker** |
| 11:00-11:25 | Harmonizing Guidelines on the Use of Real World Data for Post-Approval Observational Safety Studies for Medicines: Background, Status and Future of ICH M14 | David Moeny/Acting Deputy Director, USFDA |
| 11:25-11:50 | Hybrid Controls Design and Regulatory Landscape in EU, China and Japan | Luan, Jingyu, Senior Director, AstraZeneca |
| 11:50~12:15 | Use of Real World Data for Regulatory Decision-making in Korea | Bonggi Kim, Director, KIDS KOREA |
| 12:15-12:30 | Q & A | All |
| 12:30-13:30 | Lunch | |
| Session III | Opportunities and Challenges for Decentralized Clinical Trials (DCTs) through the Lense of Regulatory Science | **Chair**<br>HeaYoung Cho, Prof. CHA University<br>JoonWoo Bahn, Director, Asan Medical Center |
| **Time** | **Topic** | **Speaker** |
| 13:30-13:55 | Experience of DCTs and Regulatory Challenges Encountered by Investigators | KyungSang Yu, Prof. Seoul National University |
| 13:55-14:20 | De-centralised Clinical Trials | Greg Jordinson, Associate Director, Mphil, Johnson & Johnson |
| 14:20-14:45 | Regulatory Considerations for DCT in Korea | JeongYeon Kim, Director, MFDS KOREA |
| 14:45-15:00 | Q & A | All |
| 15:00-15:30 | Coffee Break | |
| Session IV | Regulatory Science in the Era of Therapeutic Transformation with Cell & Gene Therapy | **Chair**<br>JeeWon Jeong, Director, MFDS<br>YeoWon Sohn, Prof.Sung Kyun Kwan University |
| **Time** | **Topics** | **Chair / Speaker** |
| 15:30-15:55 | Regulatory Updates for Advanced Biological Products | JinWook Kang, Deputy Director<br>MFDS KOREA |
| 15:55-16:20 | Innovation Through Collaboration: Challenges in CGT Development and How the Field Can Partner With Health Authorities to Bring Transformation Products to Patients | Dylan Bechtle, Associate Director, Johnson & Johnson |
| 16:20-16:50 | Clinical Regulatory Considerations and Recent FDA Perspectives on Cell and Gene Therapy (CGT) Development | Steve Winitsky, Vice President, Parexel International |
| 16:50-17:05 | Q & A | All |
| 17:05-17:15 | Closing | InSook Park, Director General ,KRSC |

**REGISTRATION FORM :** Register online or forward to DIA
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## 2023 KRSC-DIA Workshop

**Event #23380 • December 5, 2023** | Auditorium in central post office , Seoul, Korea (서울 중앙 우체국 10 층 대강당)

## REGISTRATION

Register online at the link below or complete this registration from and email to our Korea Office

### Online Regstration

For Payment via Credit Card, please access here

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| | | | REGISTRATION FEE (KRW) |
|---|---|---|---|
| MEMBER | Academic | Early Bird (until Nov. 21, 2023) | ❑ 130,000 |
| | | After Nov. 22, 2023 | ❑ 180,000 |
| | Government | Early Bird (until Nov. 21, 2023) | ❑ 130,000 |
| | | After Nov. 22, 2023 | ❑ 180,000 |
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| | Government | Early Bird (until Nov. 21, 2023) | ❑ 180,000 |
| | | After Nov. 22, 2023 | ❑ 230,000 |
| | Industry | Early Bird (until Nov. 21, 2023) | ❑ 250,000 |
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**Please check the applicable category:**

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Last Name

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Degrees ❑ Dr. ❑ Mr. ❑ Ms.

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Address (As required for postal delivery to your location)

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## CONTACT INFORMATION

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## PAYMENT DETAILS

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## DIA Terms and Conditions

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**Member or Nonmember = 100,000 KRW**
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**(Member or Nonmember) = 50,000 KRW**

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.

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Signature Date

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