MINISTRY OF FOOD AND DRUG SAFETY
National Institute of Food and Drug Safety Evalution

DIA

NIFDS-DIA Conference 2022

New Logics of High-Tech Drug Development and Quality Challenges

17-18 November

Venue Conference A. Sky 31 Convention. Seoul, South Korea

As science and technology advance, pharmaceutical regulatory science is evolving in a way that minimizes uncertainty in the development process and shapes an environment where the actual data use.

The Regulatory Agencies around the world are moving from the traditional approach of determining the drug characteristics and QC based on the test results conducted in the development stage to drug monitoring throughout the lifecycle utilizing RBM, RWE etc. In the case of generic dosage & formulation development applying various advanced technologies, a bioequivalence evaluation considering the formulation characteristics is essential. This provides the basis for the safe use of drugs in Korea where the proportion of generics is high.

In this two-day workshop, we would like to share vivid examples from the industry along with the voices of regulatory agencies on continuous quality management throughout the drug life cycle, actual use of data, and equivalence evaluation reflecting the formulation characteristics, which are currently being actively discussed in accordance with the advancement of technology.

Key Topics

- Risk-based quality management
- Complex Generic development
- Pharmacometrics in the drug development process
- RWD/RWE in the life cycle of drug

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Kyung Won Seo
Director General
NIFDS

Younjoo Park
Director General of Drug Evaluation Department
NIFDS

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Professor - CHA University

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Director of Pharmaceutical Standardization Division
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So Hee Kim
Director of Bioequivalence Evaluation Division
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AGENDA | Day 1 | 17th November 2022

9.30–10.30	Registration
10:30-10:40	**Welcome Remarks**
	Kyung Won Seo Director General NIFDS
	Barbara Kunz Global Chief Executive & President DIA
10:40-11:00	**Keynote**
	Younjoo Park Director General of Drug Evaluation Department NIFDS
Session 1	**Quality Control through technological advancement**

Session Chair

Mijeong Kim
Director of Pharmaceutical Standardization Division
NIFDS

The new paradigm of quality in the biopharma will be updated on the evolving regulatory landscape and innovative manufacturing technology. In this session, we will discuss scientific risk-based quality management which is enabled by advanced manufacturing technology, digital technology, and a stable supply chain after the pandemic followed by management strategies for genotoxic impurities.

11:00-11:30	**Development of Continuous Manufacturing Process (Q13)**
	Yoshihiro Matsuda Senior Scientist (for Quality) (PMDA)
11:30-12:00	**The Ongoing Revision of ICH Q9 on Quality Risk Management and PQS Effectiveness Considerations**
	Kevin James O'Donnell Market Compliance Manager Health Products Regulatory Authority (HPRA)
12:00-12:30	**New Challenges on Quality Control upon High-Tec**
	HyangWon (Harriet) Min Vice President - Regulatory Affairs Asia Pacific Janssen
12:30-13:00	**Regulatory Perspective on Managing Nitrosamine Impurities –MFDS**
	Jaehyun Park Senior Reviewer - Pharmaceutical Standardization Division NIFDS
13:00-14:00	Lunch

AGENDA | Day 1 | 17th November 2022

Session 2 — Development strategy of complex generics

Session Chair
So Hee Kim
Director - Bioequivalence Evaluation Division
NIFDS

The challenges faced with complex generics development using advanced technology such as liposome, micelle, transdermal patch and metered dose inhalers etc., we will discuss the characteristics of the active ingredient and formulation to prove equivalence to a reference drug in terms of efficiency, safety, and quality. The regulatory landscape and case studies will be discussed.

14:00-14:30	**Development of Complex Generics in US** **Markham Luke** Director - Division of Therapeutic Performance I Office of Research and Standards Office of Generic Drugs - CDER US FDA
14:30-15:00	**Statistical Design Challenges Inherent in Bioequivalence Assessment of Complex Generics** **Jessica Kim** Team Leader- Generic Drugs Team 1 Office of Biostatistics Office of Translational Science Center for Drug Evaluation and Research U.S. FDA
15:00-15:15	Tea/Coffee break
15:15-15:45	**New Concept in the Method of Equivalence Study and Cases** **Choongyul Ahn** Senior Reviewer of Bioequivalence Evaluation Division NIFDS
15:45-16:15	**Case Studies: Liposomes and Nanoparticles** **Younghwan Park** CEO & Founder SN BioScience Inc.
16:15	**Closing Remarks** Session Chair **Mijeong Kim** Director of Pharmaceutical Standardization Division NIFDS

AGENDA | Day 2 | 18th November 2022

Session 3	Innovative Approaches and Quantitative Sciences in Drug Development

Session Chair
Jee Eun Lee
Vice President - Senior Research Fellow
LG Chem, Life Sciences
Innovative drug development aims to improve not only time efficiency or cost effectiveness but also the quality of presentation of a drug product by maximizing its potential benefits that outweighs the risks. Quantitative data sciences including pharmacometrics have grown drastically due to their contribution to achieving such aims. Recent examples of innovative approaches in drug development will be presented and how quantitative sciences can be utilized in decision making and drug approval will be discussed.

9.00–9.05	Welcome
9:05-9:45	**The Role of Quantitative Sciences in Pandemic Preparedness and Global Health Product Development** **Steven Kern** Deputy Director Quantitative Sciences Bill & Melinda Gates Foundation
9:45-10:25	**Role of Pharmacometrics in Drug Development Process** **Jee Eun Lee** (FDA Alumni) Vice President - Senior Research Fellow LG Chem, Life Sciences
10:25-10:40	Coffee/tea Break
10:40-11:20	**The Need for Better Approaches in Oncology Drug Development** **Geoffrey Kim** (FDA Alumni) Vice President - Applied innovation BeiGene USA
11:20-12:00	**Application of Pharmacometrics in Drug Development: a Case Study** **Jae Yeon Kim** Senior Director Early Development Oncology Pharmacometrics Novartis USA
12:00-13:00	Lunch

AGENDA | Day 2 | 18th November 2022

Session 4 — Townhall PMDA & MFDS | Using RWD/RWE in the Life Cycle of a Drug - Japan, Korea

Session Chair
Sora Lee
Vice President - General Manager Korea
Clinical Solutions, Syneos Health

The evolving landscape of Real World Data (RWD) and the use of machine learning & analytics platforms to generate Real World Evidence (RWE) are becoming important for regulatory decision-making. Learn how FDA, EMA, PMDA, and MFDS regulators' current uses of RWE/RWD and how they can be applied for other applications. Recognize general considerations and key features of successful RWE studies acceptable to the regulators for effective decision-making. Gain deeper insights with case studies and live examples of utilizing RWD/RWE at the major stages of the drug life cycle shared by industry speakers.

13:00-13:40	**Using RWD/RWE in the Life Cycle of a Drug - Japan** **Shun Tezuka** PMDA
13:40-14:20	**System Maintenance for RWD/RWE Based on Evidence and Case Study in Korea** **Wonim Do** Senior Reviewer - Cardiovascular & Neurology Products Division NIFDS
14:20-15:00	**Using RWD/RWE in the Life Cycle of a Drug – Case Study - Japan** **Bruce Crawford** Vice President - RWE Syneos Health
15:00-15:40	**Using RWD/RWE in the Life Cycle of a Drug - Case Study – China** **Xun Liu** Head of Medical & Regulatory Affairs Sandoz China
15:40-16:00	Tea/ Coffee Break

Session 5 — Townhall FDA & EMA | RWE/RWD Regulatory Update and Case Study

Session Chair
Choon Oh
CTO & Executive Vice President
Chong Kun Dang Pharmaceutical Corp.

16:00-16:40	**Leveraging Real-World Data/Evidence in Regulatory Science** **Tae Hyun Jung** Senior Statistical Reviewer Office of Translational Science, Office of Biostatistics Center for Drug Evaluation and Research U.S. Food and Drug Administration (USFDA)
16:40-17:20	**Using RWD/RWE in the Life Cycle of a Drug - EU** **Kelly Plueschke** Scientific Administrator - EMA
17:20-17:50	**Using RWD/RWE in the Life Cycle of a Drug - Case Study** **Jeff Lange** Associate Director - Center for Observational Research Amgen, Hong Kong
17:50	**Closing Remarks** **So Hee Kim** Director - Bioequivalence Evaluation Division, NIFDS

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Event I.D. 22654 | November 17-18, 2022 | Venue : Conference A. Sky 31 Convention. Seoul, South Korea

MEETING MANAGER (S)

Kanchan Patel, Associate Director India, Singapore Operations, DIA
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CANCELLATION POLICY: ON OR BEFORE OCTOBER 31, 2022

- Cancellations must be in writing and received by OCTOBER 31, 2022. Registrants who do not cancel in writing by that date and do not attend the event will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations.
- DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.
- UPON CANCELLATION, the administrative fee that will be withheld from refund amount is 25 % of the delegate fee

FULL MEETING CANCELLATION

- All refunds will be issued in the currency of the original payment

For more details, please visit : www.diaglobal.org or contact kanchan.patel@diaglobal.org

REGISTRATION FEES FOR TWO DAYS WORKSHOP

(Registration fee includes refreshment breaks and luncheons.)

Early Bird (Until October 31, 2022)

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	Registration Fee (KRW)
Industry - Member	300.000 ❑
Industry Non-Member	350,000 ❑
Academia	250,000 ❑
Government	170,000 ❑

Standard Rates (After October 31, 2022)

(Subject to Payment Realization)

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Government	220,000 ❑

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