DIA

Korea Regulatory Science Center

DIA-KRSC Workshop 2024

Advancing Regulatory Science of Innovative Medicines for Global Convergence

26 September 2024
The-K Hotel Seoul, Korea

Overview

Since the COVID-19 pandemic, the development of medical products based on the latest innovative technologies has accelerated, and the global pharmaceutical market is expanding rapidly. This has made regulatory science more important than ever.

The Korea Regulatory Science Center (KRSC) and DIA jointly organized a workshop entitled "Advancing Regulatory Science of Innovative Medicines for Global Convergence". With 2024 KRSC-DIA Workshop on September 26th in Seoul, immediately following the 2024 DIA Asia Meeting, will provide you with a unique opportunity to discuss the regulatory perspectives and innovations first hand.

The topics in each session:

Session I : Regulatory science perspective on Drug development using innovative tools- Current status and future directions of regulatory science for innovative medicines. Regulatory convergence and exchange of information on the regulatory framework and any proposed changes from US, Europe, and Asian countries.

Session II : Advancing Pharmacovigilance - Regulatory Use of Database and Risk Management Plan.

Session III : Regulatory Science Strategies and Case Study for Innovative Drug Development. In-depth quality control and safety assessment strategies for innovative new drugs.

Objective:

- Gain a comprehensive understanding of the latest innovations and changes in the biohealth sector, including medical product development
- Get updates on global regulatory policies, review processes, and safety assessments for innovative new drugs
- Get insight into the safety measures in place to protect people during the development and use of innovative medicines
- Discuss the future of the regulatory science of medicines using cutting-edge technologies
- Accelerating the development of innovative medicines through regulatory science collaborations

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AGENDA | September 26, 2024 | ALL TIMINGS IN KST

8.30 – 9.00 am	Registration
9.00 – 9.10 am	**Opening Remarks**
	In-sook Park, Director General, KRSC, Korea
9.10 – 9.20 am	**Congratulation Remark**
	Young Joo Park, Vice President, Korea, Singapore, and Southeast Asia, DIA Global **Yunhong Noh**, President, KPBMA, Korea
9.20 am – 12.20 pm	**Session 1.** **Regulatory science perspective on Drug development using innovative tools**
	This session aims to explore the regulatory perspective for drug development using innovative tools including Artificial Intelligence (AI), Machine Learning (ML) and digital health technologies. We will explore how the regulatory science has advanced to foster innovation while protecting public health. The session will cover the regulatory framework progress in this area and panel session will provide the various insights on regulatory challenges and future direction.
Session Chairs	**Kyungwon Seo** Professor Dongguk University **Younglim Kim** Director General, Drug Evaluation Department, MFDS
9.20 – 9.40 am	Opportunities and challenges in Clinical Trial Innovation
	Meghana Chalasani, FDA/CDER/OND Associate Director for Clinical Trial Innovation, USA
9.40 – 10.00 am	The European Medicines Agency's scientific guidelines on artificial intelligence to help medicine developers for prepareing marketing authorisation applications
	Susan Sandler, Director, Global Regulatory Policy & Intelligence, Janssen Research & Development, UK
10.00 – 10.20 am	AI and Drug Development – Industry point of view
	Hironobu Saito, Appointed Professor, Tottori University, Japan
10.20 – 10.40 am	Updates of medical product regulation in relation to innovative technology in Korea
	Sohee Kim, Director, Cardiovascular & Neurology Products Division, MFDS, Korea
10.20 – 10.40 am	Current state of innovative tools utilization in drug development, clinical trial and registration in Korea
	Junhee Pyo, Vice Chief, Convergence AI Institute for Drug Discovery, KPBMA, Korea
11.00 – 11.30 am	**Coffee Break & Networking**
11.30 am – 12.20 pm	**Panel Discussion + Q&A**
	Chair : **Kyungwon Seo,** Dongguk University Panellists: **Meghana Chalasani,** FDA, US **Susan Sandler,** Janssen Research & Development **Hironobu Saito,** Tottori University **Hae Sun Suh,** Kyunghee Univesity **Minseok Kim,** JNPMEDI **Sohee Kim**, MFDS **Junhee Pyo**, KPBMA
12.20 – 1.40 pm	**Lunch & Networking**
12.20 - 12.35 pm	Lunch Seminar : AI-powered Smartwatch for Personalized Medication Management Solution
	Hwiwon Lee, Founder and CEO, InHandPlus, Korea

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1.40 – 3.45 pm	**Session 2.** **Advancing Clinical Development and Pharmacovigilance: regulatory use of database and Risk Management Plan**
	This session aims to explore the evolving role of databases and Risk Management Plans (RMPs) in clinical development and pharmacovigilance to ensure the safety and efficacy of medicinal products in pre- and post-approval. Attendees will gain insights into the utilization of real-world data and advanced data analytics for regulatory decision-making, enhancing clinical development, post-marketing surveillance, and improving risk management strategies. Through case studies and regulatory perspectives from different regions, the session will highlight best practices, challenges, and future directions for integrating database studies and RMPs into clinical development and pharmacovigilance frameworks.
Session Chairs	**Min-Jung Lim** CEO MediSafe **In-sook Park** Director General KRSC
1.40 – 2.05 pm	Use cases of database study for the post-marketing surveillance in PMDA
	Takashi WAKI, Division of Pharmacoepidemiology, PMDA, Japan
2.05 – 2.30 pm	Case studies on safety information analysis and regulatory reflection using CDM
	Bonggi Kim, Director, Office of Pharmacoepidemiology and Big Data Analytics, KIDS, Korea
2.30 - 2.55 pm	RWD/RWE Real Case Studies for Enhancing Drug Development Efficiency
	Jingyu (Julia) Luan, Executive Regulatory Science Director, AstraZeneca, USA
2.55 – 3.45 pm	**Panel Discussion + Q&A**
	Chair : **Juyoung Shin,** Professor, Sungkunkwan Univesity Panellists: **Takashi WAKI,** PMDA, Japan **Bonggi Kim,** Director, KIDS, Korea **Jingyu (Julia) Luan,** AstraZeneca, USA **HyungJin Jung**, Sr.Director, Janssen Korea **Younglim Kim**, Deputy Director, Biopharmaceutical Quality Management Division, MFDS, Korea **Nam-Kyong Choi**, Professor, Ewha women's University, Korea
3.45 – 4.10 pm	**Session 3.** **Regulatory Science Strategies and Case Study for Innovative Drug Development**
	This session aims to explore the regulatory science strategies and case studies essential for the innovative drug development sector. We will examine the quality review trends of advanced drugs, focusing on recent developments in CMC reviews and guidelines. The session will cover the clinical and regulatory development of platform-based drugs including synthetic peptide drugs. Additionally, case studies on clinical development and approval of innovative drugs, including cell and gene therapies will be presented.
Session Chairs	**Youngju Choi** Director General, Biopharmaceutical and Herbal Medicine Evaluation Department, MFDS **Sora Lee** Vice President, General Manager Korea, Syneos Health
3.45 – 4.10 pm	The direction of quality review for advanced drugs in Korea : Recent CMC Review Trend of Advanced Drug in Korea
	Ohseok Kwon, Deputy Director, Advanced Drug Quality Division, MFDS, Korea
4.10 – 4.35 pm	Regulatory perspectives for advanced drug in US FDA
	Radha Goolabsingh, Global Regulatory Strategy and Engagement Leader, Scientific Affairs, DIA Global, USA
4.35 – 5.00 pm	Case Study on the Application of Regulations in Clinical Development and New Drug Approval for Cell and Gene Therapies
	Abhi Gupta, Senior Vice President, Head of Cell & Gene Therapy, Syneos Health, USA
5.00 – 5.25 pm	Global CMC Regulatory Perspectives for Cell and Gene Therapy Development and Commercialization
	Allen Callaway, Director CMC Regulatory Affairs, Janssen, USA
5.25 – 5.30 pm	**Closing**

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