MFDS-DIA Workshop

Opportunities and Challenges in Drug Development and Approval

5-6 December, 2018 | Chungbuk C&V Centre, Osong KOREA

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What to prepare from early stage for global pharmaceuticals, biologics and biosimilar development.

MFDS-DIA 2018 Workshop is unique in presenting from policy and regulations to R&D both in domestic and global spaces. During an intense and stimulating two days, engage in a series of strategic discussions on current regulatory landscape in MFDS and FDA. Past two decades, Korea healthcare community has grown experiencing global product development. We have accumulated experiences learned from successes and failures.

The program is being developed and prepared to address your needs, what to prepare from early stage for global pharmaceuticals, biologics and biosimilars development. With healthcare product development becoming increasingly global, the time has come to deepen the discussion on how to leverage the individual strengths, promote better collaboration.

Program Highlights

- Regulatory perspectives – key check points
- Industry experiences on global approval – successes and failures
- How to reduce barriers from early stage development

Who should attend?

- Industry professionals in Pharmaceuticals involved in Research & Development, Regulatory Affairs, CMC, Biologics and Biosimilar, Medical Affairs and Clinical Studies
- Regulators and personnel from Health Authorities and Ministries
- Academia and Researchers

Registration

Online registration: Go to https://www.diaglobal.org/mfds

Please contact us at Korea@DIAGlobal.org, for assistant.

AGENDA | Day 1 | 5th December, 2018

08:30-09:00	Registration
09:00-09:10	**Welcome Remarks** **Sun Hee Lee** Director General of Institute MFDS
09:10-09:25	**Key Note** **NaKyung Kim** Director General of Department MFDS

Session 1 – Edge of Small Molecule Development

Session Chair
ChangWon Park
MFDS

09:25-10:25	**Challenges of First-in Class Drug Discovery: Pitfalls in Translating Science into Medicine** **Tae Young Yun** Vice President Dong-A ST
10:25-11:25	**Pharmacology and Toxicology Testing of Small Molecules from a Regulatory Perspective** **Yangmee Shin*** Sr. Pharmacologist KWiSE
11:25-11:40	Coffee/tea Break
11:40-12:40	**CMC Issues Encountered in the Long Road of New Drug Development, and our Struggles to Overcome Them** **HeeBong Lee** Vice President LG
12:40-13:40	Lunch

Session 2 – Strategy for Biosimilar Development & Approval

Session Chair
Hee Kyung Kim
Samsung Bioepis

13:40-14:40	**Challenges in the Global Clinical Development of Biological Products** **SuEun Song** Head of Clinical Operation CELLTRION
14:40-15:40	**Establishing Biosimilarity : Totality of Evidence** **Se Eun Kim** Senior Scientific Officer MFDS
15:40-15:55	Coffee/tea Break
15:55-16:55	**Global Regulatory Development Strategy of Biosimilar** **HyeJung Na** Director Samsung Bioepis
16:55-17:55	**Biosimilars: Current Status and Future Trends** **Hae-Young Ahn*** President Ahn Bio
17:55-18:05	**Day 1 Wrap Up** **Hee Kyung Kim** Sr. Vice President Samsung Bioepis

* * FDA or FDA AA

AGENDA | Day 2 | 6th December, 2018

09:00-09:15	**Key Note** **Dr. Youngju Choi** Director NIFDS MFDS

Session 3 – Check Points of Biologics Development

Session Chair
Ho-Sang Jeong
MFDS

09:15-10:10	**Considerations and Challenges on CMC-related Issues for the Early-Stage Development of Biotechnology Products** **Changjin Lee** CTO Hugel Inc.
10:10-10:25	Coffee/tea Break
10:25-11:20	**Regulatory Inspections for Data Integrity and Human Protection** **SeongEun Cho*** Director FDA
11:20-12:15	**Pharmacology and Toxicology Testing of Biologics from a Regulatory Perspective** **Yangmee Shin*** Sr. Pharmacologist KWiSE
12:15-13:15	Lunch

Session 4 – Regulatory and Industry Perspectives in Clinical Development

Session Chair
Jung Yun Chang
MFDS

13:15-14:10	**cGMP Inspection Cases-Common Findings/ Responses in Asia** **Charles Ahn*** Principal Consultant Aegisbeacon
14:10-15:10	**Differentiation Strategy for the Drugs Preclinical Development Using Orthotropic Animal Models** **Sun Jin Kim** Chairman/Founder Platbio Inc.
15:10-15:25	Coffee/tea Break
15:25-16:20	**Enhanced Early Clinical Drug Development with Advanced Tools** **Hae-Young Ahn** President Ahn Bio
16:20-17:15	**Clinical Multi-Regional Clinical Trial in Korea** **Mee Ryung Ahn** Director MFDS
17:15-17:25	**Day 2 Wrap Up** **Jung Yun Chang** MFDS
17:25-17:30	**Closing Remarks** **SangAeh Park** Director MFDS

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Event I.D. 83518 | 5-6 December, 2018 | KOREA

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예약시 식품의약품안전처 – DIA 워크숍 참가자 임을 알릴것

MEETING MANAGER (S)
Youngshin Lee, MD & SVP, DIA - Korea, ASEAN, India
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CANCELLATION POLICY: ON OR BEFORENOVEMBER 24, 2018

- Cancellations must be in writing and received by NOVEMBER 24, 2018. 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/mfds or https://www.diaglobal.org/mfds

REGISTRATION FEES FOR TWO DAYS WORKSHOP

(Registration fee includes refreshment breaks and luncheons.)

Early Bird (Until November 16th 2018)

(Subject to Payment Realization)

	Registration Fee (KRW)
Industry	300,000 ❑
Academia	300,000 ❑
Government	200,000 ❑

Standard Rates (After November 16th 2018)

(Subject to Payment Realization)

Industry	400,000 ❑
Academia	350,000 ❑
Government	250,000 ❑

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1-Year Membership	200
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