2019 DIA-NIFDS Workshop

Science Based Drug Development and Approval - Small Molecule and Biologics

21-22 August, 2019 | Chungbuk C&V Centre, Osong KOREA

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For small-molecule drugs, the path to a marketed drug is arduous and because of its complexity, drug discovery and development is widely recognized as one of the most financially risky endeavors and a major challenge for the biomedical industry. The discovery and development process for biologics even more complexed path, and success is far from certain.

In recent times biologics too have attracted much attention primarily because the commercial potential of biologics is very promising and is delivering a better overall economic return than small molecule drugs.

With this backdrop DIA-NIFDS, jointly brings to you a **Workshop on Science Based Drug Development and Approval- Small Molecule and Biologics**.

During the two days this unique workshop would encompass topics covering the spectrum of Small molecules and Biologics and keys must know from early stage development.

Be a part of the series of strategic discussions on current regulatory landscape in NIFDS and FDA and Industry perspectives from experts who have hands on experiences.

A few Key topics:

- Anticancer and Pediatric Drugs Development
- Modeling and Simulation in Drug Development
- Regulation for Cell and Gene Therapy Products
- CMC for Small and Biologics
- Bioanalysis in Drug Development

Registration

Please go to: http://diaglobal.org/Korea

or

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

AGENDA | Day 1 | August 21, 2019

8:15-8:45	**Welcome and Registration**	
8:50-9:00	**Opening Remarks**	
	Director General NIFDS MFDS	
9:00-9:20	Keynote Presentation 1 **Clinical Trials in Korea : Current Status and Future Strategies**	
	Kyung Won Seo Director General NIFDS MFDS	
9:20-10:10	Keynote Presentation 2 **Digital Transformation in Healthcare through AI**	
	Al Koh CEO, Microsoft Korea	
10:10-10:30	Coffee Break	

Session 1: Strategy and Regulatory Science of Non-Clinical Development

Session Chair
Chang Won Park
NIFDS

10:30-11:15	**Nonclinical Development of Anticancer and Pediatric Drugs: A Regulatory Perspective**	
	Yangmee Shin* KWISE	
11:15-12:00	**Strategy on Non-Clinical Development of CNS Drugs**	
	Jung-Shin Park SK Biopharmaceuticals	
12:00-13:00	Lunch	

Session 2: Orphan Drug Development and Approval in Regulatory Perspective

Session Chair
Jin-A Jung
Hanmi

13:00-13:45	**Clinical Pharmacology in Drug Development for Rare and Rare Pediatric Diseases**	
	Insook Kim*	
13:45-14:30	**Orphan Drug Designation and a Regulatory Perspective**	
	Myeong-Ah Chung NIFDS	
14:30-15:15	**Importance Of Bioanalysis in Drug Development**	
	Chongwoo Yu*	
15:15-15:30	Coffee Break	

Session 3: Impact of PK-PD Modelling and Simulation on Drug Development and Approval

Session Chair
Dong-Seok Yim
Catholic Univ.

15:30-16:15	**Regulatory Impact of Pharmacometrics**	
	Jee Eun Lee* GC Pharma	
16:15-17:00	**Application of Modeling & Simulation in Clinical Drug Development: Case Studies**	
	Holly Kimko AstraZeneca	
17:00-17:45	**PK-PD Model Based Drug Development Experienced in Korea**	
	Hyeong-Seok Lim Asan Medical Center	
17:45-18:00	**Closing Remarks**	
	HoJung Kim Director NIFDS MFDS	

AGENDA | Day 2 | August 22, 2019

9:00-9:20 Keynote Presentation 3
Present and Future Strategies for Biopharmaceuticals in Korea

Soojung Sohn
Director General NIFDS
MFDS

Session 4: Current Trends in Cell and Gene Therapy Products from Regulatory Perspective

Session Chair
Ho-Sang Jeong
NIFDS

9:20-10:05 **Clinical Development of Cellular and Gene Therapy Products**

Lei Xu*
CBER, FDA

10:05-10:50 **Regulation for Cell and Gene Therapy Products in Korea**

Kyoung Suk Choi
NIFDS

10:50-11:05 Coffee Break

Session 5: Biologics - Innovation and Challenges from CMC perspective

Session Chair
Ho Jung Oh
NIFDS

11:05-11:50 **CMC-Related Technical and Regulatory Aspects for Development of Biotherapeutic Products**

Jun Park*
Helixmith

11:50-12:35 **Antibody Drug Manufacturing and Quality Control (Tentative)**

Sangyoon Lee
Celltrion

12:35-13:30 Lunch

Session 6: Non-Clinical Safety Evaluation of Advanced Therapies

Session Chair
Jong Kwon Lee
NIFDS

13:30-14:15 **Preclinical Considerations of Cell and Gene Immunotherapy Drugs**

Kyoung-Sik Moon
KIT

14:15-15:00 **Toxicology of Immuno-oncology**

Woo Chan Son
Univ of Ulsan, Medical School

Session 7: Global Entry for New Drug Development

Session Chair
Younglim Kim
NIFDS

15:00-15:45 **CMC Information Recommended for INDs and NDAs**

Giljong Kang*
C & O Pharma Consultants

15:45-16:30 **Hanmi Footprints and Reshaping for Global Clinical Trials**

Kyounghee Seo
Hanmi

16:30-16:45 Coffee Break

16:45-17:30 **Patient Centric Drug Development and Approval: Factors Affecting Dose and Dosing Regimen**

Hae-Young Ahn*
Ahn Bio

17:30-17:45 **Closing Remarks**

Ho Jung Oh
NIFDS

*Speaker from FDA & FDA AA

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Event I.D. 83519 | August 21 -22, 2019 | Osong C&V Center, Korea

회의장: 충북 C&V Centre 충청북도 청주시 오송읍 오송생명1로 194 대회의실 (2층)
T: +65 6733 0880 | F: +65 6737 8880

호텔: 밸류호텔 세종시티 T: 043-716-1311
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MEETING MANAGER (S)
Youngshin Lee, MD & SVP, DIA - Korea, ASEAN, India
cell: 82 10 9273 4910 | youngshin.lee@diaglobal.org

Kanchan Patel, Associate Director India Operations, DIA
kanchan.patel@diaglobal.org

CANCELLATION POLICY: ON OR BEFORE AUGUST 1, 2019

- Cancellations must be in writing and received by August 1, 2019. 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 DIAglobal.org/Korea

REGISTRATION FEES FOR TWO DAYS WORKSHOP

(*Registration fee includes refreshment breaks and luncheons.)*

Early Bird (Until July 31, 2019)

(Subject to Payment Realization)

	Registration Fee (KRW)
Industry - Member	250,000 ❑
Industry Non-Member	300,000 ❑
Academia	200,000 ❑
Government	150,000 ❑

Standard Rates (After July 31, 2019)

(Subject to Payment Realization)

Industry-Member	350,000 ❑
Industry Non-Member	400,000 ❑
Academia	300,000 ❑
Government	200,000 ❑

Onsite Registration Rates

Industry-Member	400,000 ❑
Industry Non-Member	450,000 ❑

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