

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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Director General NIFDS
MFDS



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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



8:15-8:45 **Welcome and Registration**

8:50-9:00 **Opening Remarks**

Director General NIFDS
MFDS

9:00-9:20 **Keynote Presentation 1**
To Be Announced (TBA)

Kyung Won Seo
Director General NIFDS
MFDS

9:20-10:10 **Keynote Presentation 2**
Digital Transformation in Healthcare through AI

AI 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 **Non-clinical 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 Jung
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
DongSeouk Lim
Catholic Univ.

15:30-16:15 **Regulatory Impact of Pharmacometrics**

Jee Eun Lee*
Green Cross

16:15-17:00 **Application of Modeling and Simulation in Clinical Drug Development: Case Studies**

Holly Kimko
Astra Zeneca

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**

SangAeh Park
NIFDS

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

Younjoo Park
Director General NIFDS
MFDS

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

Session Chair
Ho-Sang Jeong

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*
Viomed

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

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

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MEETING MANAGER (S)

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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 21, 2019)

(Subject to Payment Realization)

	Registration Fee (KRW)	
Industry - Member	250,000	<input type="checkbox"/>
Industry Non-Member	300,000	<input type="checkbox"/>
Academia	200,000	<input type="checkbox"/>
Government	150,000	<input type="checkbox"/>

Standard Rates (After July 21, 2019)

(Subject to Payment Realization)

Industry-Member	350,000	<input type="checkbox"/>
Industry Non-Member	400,000	<input type="checkbox"/>
Academia	300,000	<input type="checkbox"/>
Government	200,000	<input type="checkbox"/>

Onsite Registration Rates

Industry-Member	400,000	<input type="checkbox"/>
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