

# 2025 BIO REGULATORY INNOVATION CONFERENCE

Roadmap to the Finish Line

2025. **04.23** (Wed) - **24** (Thu)  
Sheraton Grand Incheon Hotel



## CONFERENCE OVERVIEW

- Title 2025 BIO Regulatory Innovation Conference
- Theme Roadmap to the Finish Line
- Date April 23 (Wed) – 24 (Thu), 2025
- Venue Sheraton Grand Incheon Hotel , Songdo, Incheon, Korea
- Hosted by Korea Biotechnology Industry Organization
- Organized by The Yakup
- Supported by Ministry of Food and Drug Safety  
Korean Research-based Pharmaceutical Industry Association
- Programs U.S. Regulatory Experts' Lectures,  
Company Presentations & Experience Sharings, Networking

2025 BIO Regulatory Innovation Conference에서는 신약 개발 기업들이 글로벌 시장 진출 시 직면할 수 있는 다양한 규제와 그에 대한 대응 전략을 집중적으로 다룰 예정입니다. 특히 미국 시장에 대한 올바른 방향을 제시해서 바이오 기업들의 미국 규제에 대한 이해를 돕는 데 목적이 있습니다.

이를 해결하기 위해, 본 행사에서는 미국규제전문가와 신약 연구개발 기업 간의 교류를 통해 최신 정보를 공유하고, 규제 장벽을 효과적으로 극복할 수 있는 실질적인 팁과 노하우를 제공하고자 합니다.

이를 통해 기업들은 신약 개발의 효율성을 높이고 글로벌 경쟁력을 강화할 수 있을 것으로 기대됩니다.

여러분의 많은 참여와 관심 부탁드립니다.

## Program

### DAY 1

**April 23 (Wed) 13:00 – 21:00**

13:00 - 13:20	Opening
13:20 - 13:50	SESSION
	TBD
13:50 - 14:40	SE1 CMC Small Molecules
	<b>Strategies to Streamline CMC Development and Expedite Regulatory Clearance: Risk- and Platform- Based Approaches</b> <b>Jun Young CHOI, Ph.D.</b> (Head, Division of R&D, ST Pharm)
	Q&A (10mins)
14:40 - 15:10	Coffee Break
15:10 - 16:00	SE2 CMC Biologics
	<b>Key Regulatory and CMC Considerations for the Novel Drug Modalities</b> <b>Jun Tae PARK, Ph.D.</b> (U.S. Regulatory Expert, KHIDI)
	Q&A (10mins)
16:00 - 16:50	SE3 NON-CLINICAL Small Molecules / Biologics
	<b>Current Nonclinical Testing Paradigm for Drug Development: A Regulatory Perspective</b> <b>Yangmee SHIN, Ph.D.</b> (U.S. Regulatory Expert)
	Q&A (10mins)
16:50 - 17:00	Break
17:00 - 18:00	PANEL DISCUSSION
	Moderator <b>Sun Hee LEE, Ph.D.</b> (Ewha Womans Univ.)
18:00 - 19:00	Networking Reception
19:00 - 21:00	Networking Dinner

\* Conference programs are subject to change.

## Program

### DAY 2

**April 24 (Thu) 09:00 – 13:00**

09:00 - 09:30	<div>CS Small Molecules Development &amp; Approval</div> <div><b>XCOPRI: U.S. Commercialization, Meaningful Success, and Next Steps</b> <b>Mr. Donghoon LEE</b> (CEO &amp; President, SK Biopharmaceuticals Co., Ltd. and SK Life Science, Inc.)</div>
09:30 - 10:20	<div>SE4 CLINICAL Small Molecules / Biologics</div> <div><b>Clinical Development Strategy: The Good and The Ugly</b> <b>Sang Mok CHUNG, Ph.D.</b> (U.S. Regulatory Expert, BIOSTAR)</div> <div>Q&amp;A (10mins)</div>
10:20 - 10:40	Coffee Break
10:40 - 11:30	<div>SE5 REGULATORY</div> <div><b>Regulatory Strategies in Successful Drug Development and Approval</b> <b>Hae-Young AHN, Ph.D.</b> (U.S. Regulatory Expert, AhnBio Consulting)</div> <div>Q&amp;A (10mins)</div>
11:30 - 12:30	<div>PANEL DISCUSSION</div> <div>Moderator <b>Sun Hee LEE, Ph.D.</b> (Ewha Womans Univ.)</div>
12:30 - 13:00	Closing

## Moderator & Speakers



**이선희**  
**Sun Hee LEE, Ph.D.**

Ewha Womans Univ.  
Regulatory science expert member of  
the National Bio-Pharmaceutical Commission

Moderator

### CMC Small Molecules



Strategies to Streamline CMC  
Development and Expedite  
Regulatory Clearance:  
Risk- and Platform- Based Approaches

**최준영**  
**Jun Young CHOI, Ph.D.**

Head, Division of R&D, ST Pharm

Speaker / Panel

### CMC Biologics



Key Regulatory and  
CMC Considerations  
for the Novel Drug Modalities

**박준태**  
**Jun Tae PARK, Ph.D.**

U.S. Regulatory Expert, KHIDI

Speaker / Panel

### Non-clinical (Small Molecules / Biologics)



Current Nonclinical Testing Paradigm  
for Drug Development  
: A Regulatory Perspective

**신양미**  
**Yangmee SHIN, Ph.D.**

U.S. Regulatory Expert

Speaker / Panel

### Clinical (Small Molecules / Biologics)



Clinical Development Strategy  
: The Good and The Ugly

**정상목**  
**Sang Mok CHUNG, Ph.D.**

U.S. Regulatory Expert, BIOSTAR

Speaker / Panel

### Regulatory



Regulatory Strategies  
in Successful Drug Development  
and Approval

**안해영**  
**Hae-Young AHN, Ph.D.**

U.S. Regulatory Expert,  
AhnBio Consulting

Speaker / Panel

### Small Molecules Development & Approval



XCOPRI: U.S. Commercialization,  
Meaningful Success,  
and Next Steps

**이동훈**  
**Mr. Donghoon LEE**

CEO & President, SK  
Biopharmaceuticals Co., Ltd.  
and SK Life Science, Inc.

Speaker