

# CERTAINTY

## By CERTARA®

### GREATER CERTAINTY IN DRUG DEVELOPMENT

다가오는 9 월 18 일 여의도 IFC 콘래드 서울 호텔에서 서타라 코리아가 주최하는 Certara Certainty Korea 2025 가 개최됩니다.

본 행사에서는 제약바이오 기업 및 글로벌 과학 / 규제 전문가분들을 초청하여 FDA 규제 전략 사례부터 신약개발에 서 임상약리학의 역할, 그리고 혁신적인 신약 개발 전략의 최신 트렌드에 이르기까지 앞으로의 신약개발에서 필수적으로 고려해야 할 핵심 사항들을 다룹니다.

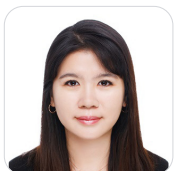
#### 고객 연사



**10:15 - 10:40**

#### **Case Study on FDA Regulatory Strategies for Biotechnology Startups**

박진영, PM, 차장, (주)큐라클



**12:00 - 12:25**

#### **The Role of Clinical Pharmacology in New Drug Development**

이현아, PhD, 전문, 임상약리, 삼성바이오에피스



**14:20 - 14:45**

#### **PBPK Case Studies: Accurate FIH Predictions for Small Molecules**

손종철, PhD, 차장, 비임상연구팀, 대웅제약

#### 서타라 강연 – 일부 발췌



**9:45 - 10:15**

#### **FDA Regulatory Strategy: Do, Don'ts and Insight**

Oxana Iliach, PhD, Senior Director, Regulatory Strategy, Certara



**10:40 - 11:10 / 16:15 - 16:45**

**Designing a High-Value Drug Development Program: From Concept to First-in-Human / Commercial Considerations for Early Development – Setting the Destination**

Tong Zhu, PhD, VP, Global Head, Clinical Pharmacology & Translational Medicine Certara Drug Development Solutions



**11:30 - 12:00**

**Translating QSP from Discovery to the Clinic: Applications, Regulatory Impact, and a Sneak Peek at Certara IQ**

Joshua Apgar, PhD, Vice President, Head of QSP, Certara



**12: 25 - 12:45**

**Ready for AI? Preparing for the Next Era of Drug Development**

Jiwon Hur, MD, AI APAC Solutions Consultant, Certara



**12:45 - 13:00 / 15:55 - 16:15**

**The Certara Platform: Advanced Technology to Increase Certainty in Drug Discovery and Development / Mind the Gap: Strategic Approaches for Phase 1 Success**

Heeyoung Kim, Director, APAC Solutions Consultant team, Certara



**14:45 - 15:15**

**PBPK Models – Novel Case Studies and The Latest Trends**

Noriko Okudaira, PhD, Senior PBPK Consultant, Certara



**15:35 - 15:55**

**From Target to IND: How Early Mechanistic Modeling Drives Strategic Decision Making**

Katie Williams, PhD, Senior Director, Global Portfolio Leader, Certara

## CERTAINTY 이벤트 개요

- 날짜: 2025년 9월 18일(목)
- 시간: 9:30am – 4:50pm (9:00am 등록 오픈)
- 장소: 콘래드 서울 호텔 6층 Studio I-III, 서울특별시 영등포구 국제금융로 10, IFC 서울
- 준비물: 명함 (행사 당일 등록데스크에 명함 1장을 제출해 주시기 바랍니다)
- 주차: 호텔 지하 무료 주차(등록 데스크에서 차량 번호 등록)
- 기타: 참가자분들께 식음료와 기념품을 제공해 드립니다

## SCHEDULE

TIME	SESSION	SPEAKER
9 : 00	Reception open	
9 : 30	Opening & Introduction	<b>Junyong Lee</b> Country Commercial Director, Certara Korea
9 : 45	FDA Regulatory Strategy: Do, Don'ts and Insight	<b>Oxana Iliach, PhD</b> Senior Director, Regulatory Strategy, Certara
10 : 15	Case Study on FDA Regulatory Strategies for Biotechnology Startups	<b>Jinyoung Park, PM</b> Deputy Director, CURACLE Co., Ltd.
10 : 40	Designing a High-Value Drug Development Program: From Concept to First-in-Human	<b>Tong Zhu, PhD</b> Vice President, CPTM, Certara
11 : 10	Coffee break	
11 : 30	Translating QSP from Discovery to the Clinic: Applications, Regulatory Impact, and a Sneak Peek at Certara IQ	<b>Joshua Apgar, PhD</b> Vice President, Head of QSP, Certara
12 : 00	The Role of Clinical Pharmacology in New Drug Development	<b>HyunA Lee, PhD</b> Sr. Manager, Clinical Pharmacology, Samsung Bioepis
12 : 25	Ready for AI? Preparing for Next Era of Drug Development	<b>Jiwon Hur, MD</b> AI Solutions Consultant, APAC, Certara
12 : 45	The Certara Platform: Advanced Technology to Increase Certainty in Drug Discovery and Development	<b>Heeyoung Kim</b> Director, Solutions Consultant, APAC, Certara
13 : 00	Lunch & Demo booth	
14 : 20	PBPK Case Studies: Accurate FIH Predictions for Small Molecules	<b>Jong Cheol Shon, PhD</b> New Drug PK Part Leader, Daewong Pharmaceuticals
14 : 45	PBPK Models - Novel Case Studies and The Latest Trends	<b>Noriko Okudaira, PhD</b> Senior PBPK Consultant, Certara
15 : 15	Coffee break	
15 : 35	From Target to IND: How Early Mechanistic Modeling Drives Strategic Decision Making	<b>Katie Williams, PhD</b> Senior Director, GPL, Certara
15 : 55	Mind the Gap: Strategic Approaches for Phase 1 Success	<b>Heeyoung Kim</b> Director, Solutions Consultant, APAC, Certara
16 : 15	Commercial Considerations for Early Development – Setting the Destination	<b>Tong Zhu, PhD</b> Vice President, CPTM, Certara
16 : 45	Closing & Group Photo	<b>Roger Williams</b> Vice President, Asia Pacific, Commercial, Certara
16 : 50	Event ends	

### Certara 소개

Certara는 독점적인 바이오시뮬레이션 소프트웨어, 기술 그리고 서비스를 통해 전통적인 물질발견과 약물개발을 혁신하여 의학발전을 가속화하도록 지원합니다. Certara의 고객으로는 전 세계 70 개국에 걸쳐 2,400 개 이상의 글로벌 바이오 제약 회사, 선도적인 학술 기관 및 주요 규제 기관들이 있습니다.