CERTAINTY By CERTARA

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 앞으로 의 신약개발에서 필수적으로 고려해야 할 핵심 사항들을 다룹니다 .

고객 연사

Jinyoung Park, PM

Deputy Director, CURACLE Co., Ltd.

Jinyoung Park, PM, majored in Animal Biotechnology and began his career in clinical trials at a local pharmaceutical company. He subsequently worked as a Clinical Research Associate and Project Manager at both local and global CROs, and currently serves as a Project Manager in the Clinical Development Division at the biotech venture Curacle.

Session: Case Study on FDA Regulatory Strategies for Biotechnology Startups

HyunA Lee, PhD

Senior Manager, Clinical Pharmacology, Samsung Bioepis

Hyuna Lee, PhD, is a Clinical Pharmacologist at Samsung Bioepis with over 10 years of clinical experience and 15 years of expertise in MIDD, including PBPK and PopPK/PD modeling. Previously at Daewoong Pharmaceutical, she established the PBPK platform in the Korean industry. She earned her MS in Biomathematics with a focus on PBPK from North Carolina State University and her PhD in Clinical Pharmacology from Seoul National University.

Session: The Role of Clinical Pharmacology in New Drug Development

Jong Cheol Shon, PhD

New Drug PK Part Leader, Daewoong Pharmaceutical

Jong Cheol Shon, PhD, is Principal Researcher and Part Leader of the Preclinical PK Group at Daewoong Pharmaceutical. He has conducted ADME and PK research on small molecules and biosimilars for over six years at national research institutes and pharmaceutical companies. He has published over 30 articles in analytical chemistry, pharmaceutical sciences, and metabolomics, and currently serves as a Government project reviewer.

Session: PBPK Case Studies: Accurate FIH Predictions for Small Molecules

서타라 강연 – 일부 발췌

Oxana Iliach, PhD

Senior Director, Regulatory Strategy, Certara

Oxana Iliach, PhD, has over 15 years of experience in the healthcare industry, including more than 10 years in regulatory affairs. She specializes in global regulatory strategy and drug development for rare diseases, paediatrics, and biosimilars, with a focus on Chemistry, Manufacturing, and Control (CMC). She has hands-on experience with regulatory meetings and various types of submissions to EMA, FDA and Health Canada.

Session: FDA Regulatory Strategy: Do, Don'ts and Insight

Tong Zhu, PhD

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

Tong Zhu, PhD, has over 25 years of experience specializing in translational medicine, early development, and clinical pharmacology. She has a wealth of knowledge in pharmaceutical research and development. Tong previously led global mitochondrial biology drug development strategies during her 14-year tenure at Astellas, where she held leadership roles in Clinical Pharmacology and Exploratory Development. Earlier, she advanced through Abbott/AbbVie's Clinical Pharmacology and Pharmacometrics teams.

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

Joshua Apgar, PhD

Vice President, Head of QSP, Certara

Joshua Apgar, PhD, is Vice President VP, Head of QSP Software at Certara. Joshua received his PhD in Biological Engineering from MIT. He is a co-founder of Applied BioMath (acquired by Certara in Dec 2023). He is dedicated to reducing interruptions in the late stages of drug development by leveraging physics-based models to convert in vitro and in vivo data, evaluating target feasibility, understanding drug mechanisms of action, and predicting human dosing.

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

Jiwon Hur, MD

AI APAC Solutions Consultant, Certara

Jiwon Hur, MD, is AI APAC Solutions Consultant at Certara. At the intersection of healthcare and innovation, Jiwon brings a unique perspective to the evolving challenges of drug development. With experience navigating the complexities of delivering innovative therapies to patients, Jiwon is now focused on advancing AI-driven solutions that accelerate drug development and drive meaningful innovation across the life sciences industry.

Session: Ready for AI? Preparing for the Next Era of Drug Development

Heeyoung Kim

Director, APAC Solutions Consultant team, Certara

Heeyoung Kim has over 16 years of experience in the clinical industry, contributing significantly to advancements in drug development. As a trusted advisor, her career reflects a commitment to enhancing clinical operations and the drug development lifecycle through innovative solutions and effective communication of industry trends. Her primary focus is identifying gaps between the current state and the industry's goals, then finding solutions to achieve unmet targets. She influences market stakeholders to better understand new global trends and regulatory updates. Looking ahead, Heeyoung aims to continue improving drug development processes by introducing new technical insights and methodologies to advance the industry.

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

Noriko Okudaira, PhD

Senior PBPK Consultant, Certara

Noriko Okudaira, PhD, is a Senior PBPK Consultant at Certara, specializing in physiologically-based pharmacokinetic (PBPK). She earned her PhD from the University of Tokyo and studied under Professor L. Benet at the University of California. With extensive experience at leading companies like Roche Japan, Meiji Seika, and Daiichi Sankyo, Noriko guides clients on utilizing PBPK models throughout drug development, ensuring informed decision-making and successful outcomes in their research.

Session: PBPK Models – Novel Case Studies and The Latest Trends

Katie Williams, PhD

Senior Director, Global Portfolio Leader, Certara

Katie Williams, PhD is a Senior Director at Certara. Katie received her PhD in Applied Mathematics from the University of Arizona and spent 7 years building QSP models including at Takeda and a Boston start-up called Applied BioMath before moving over to business development to help scale Applied BioMath (acquired by Certara in 2023). Katie leads the mechanistic modeling commercial team.

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