

TUESDAY, SEPTEMBER 22, 2020 | Symposium 9 | 12:00 – 1:30 PM

Building Bridges: Combination of Product Drug/Device Development With Biologics

DRUG DEVELOPMENT TRACK

Offers both CME & CPE Credit

UAN #JA4008220-0000-20-021-H04-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Jocelyn H. Leu, PharmD, PhD, Scientific Director, Janssen Research & Development LLC

Yow-Ming Wang, PhD, Associate Director, Biosimilars & Therapeutic Biologics, Clinical Pharmacology, CDER, US Food & Drug Administration

TARGET AUDIENCE:

This Symposium will be useful for primary care and specialty physicians, pharmacists, clinical pharmacologists, clinical research associates, basic scientists and other healthcare professionals with an interest in learning about the development of combination products for biologics.

GOALS & OBJECTIVES:

Following the completion of this activity, the learner will be able to:

1. Recognize the industry and agency perspectives on clinical pharmacology strategies for the development of combination products;
2. Discuss considerations in designing the bridging approach and assessing the bridging data for combination products;
3. Identify the opportunities for pharmacokinetic/pharmacodynamic analyses to demonstrate clinical relevance for the development of combination products;
4. Identify the opportunities for clinical pharmacologists and pharmacometricians in the development of combination products.

Combination Product Bridging: Using the Right Tools

Suzette Roan, JD, Senior Director, Regulatory Affairs, Devices & Combination Products, Sanofi

Relevance of Bioequivalence Studies for Bridging from Prefilled Syringe to Autoinjector for Monoclonal Antibodies

Kenneth Kulmatycki, BSc Pharm, PhD, Director, Novartis Inst for Biomedical Research

Challenges & Opportunities in Building the Scientific Bridge: Case Studies

Jocelyn H. Leu, PharmD, PhD, Scientific Director, Janssen Research & Development LLC

Building the Bridge for Biologic Drug/Device Combination Products: Regulatory Perspectives

Yow-Ming Wang, PhD, Associate Director, Biosimilars & Therapeutic Biologics, Clinical Pharmacology, CDER, US Food & Drug Administration

Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation