SEKISUI XENOTECH

DRUG METABOLISM

DEVELOPMENT AND RISK ASSESSMENT

SEMINARS

Moving Forward in Drug Development:

Updates in Metabolism Testing

San Diego
Wednesday May 1, 2019

Green Acre Campus Pointe
10300 Campus Point Drive
San Diego, CA 92121

Agenda:

3:00 – 3:30 Welcome Reception and Networking

3:30 - 4:30 Presentations

4:30 – 5:30 Cocktails, Discussion and Meet the Speakers

Event is free of charge to attend

Sekisui XenoTech is pleased to announce its Drug Metabolism Technical Seminar Series with upcoming 2019 dates and venues.

These fully interactive events provide in-depth presentations from industry experts. We will cover various topics around pharmaceutical preclinical testing with specifics on how to effectively move compounds through the development pipeline.

A special presentation will be provided by Dr. Larry Wienkers, of Wienkers Consulting, LLC.

Keynote Address: **"Drug Metabolism Related Safety Considerations in Drug Development."**

Abstract: Approximately 30 years ago, sub-optimal DMPK properties were recognized as the primary contributor to the failure (~40%) of potential new therapies in early clinical trials. This observation precipitated a renaissance period across the discipline which served to improve DMPK efforts within discovery and in vitro testing. As a consequence, the failure rate for new chemical entities due to poor DMPK attributes is currently below 5%. Additionally, in 2017 the FDA released a guidance for in vitro testing of drug candidates highlighting the importance of illuminating potential drug-drug interaction (DDI) prior to IND submission. While the success of DMPK groups to resolve issues is impressive, there is still a critical need to tailor testing to understand the activity and safety implications of key drug metabolites as part of the overall evaluation of the NCE. This overview will touch upon strategies for building phase-appropriate packages identifying metabolites to account for pharmacological activity, potential DDI, and associated metabolism-dependent drug safety concerns.

A complementary presentation will follow, presented by Dr. Brian Ogilvie, Ph.D., Vice President of Scientific Consulting at Sekisui Xenotech: **Metabolite Identification: Now Even Earlier**

This brief discussion will outline applications of in vitro studies to identify metabolites, and the importance of tailored study designs updated to address needs for evaluating the DDI potential of a drug candidate and its metabolites, as detailed in the 2017 guidance released by the FDA.

Contact Sekisui XenoTech representative Kelsey Pigg for more information

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