WORKSHOP

Vancouver-Pharmaceutical & BioScience Society

Preclinical Development & IND/CTA Filings: Nuts, Bolts and Best Practices: DAY 1

Event Time: October 9th, 2019
Check-in, Networking & Vendor show: 11:00 am-12:00 pm;
Lunch: 12:00-12:30 pm; Workshop: 12:30-3:30 pm

Location: The Floral Hall at VanDusen Gardens, Oak St. at 37th Ave, Vancouver. Parking is free.

General Registration: www.PBSS.org

Sponsorship: CDN$350 for vendor show.

Fees: Half- Day Workshop CDN$89 registration online (CDN$109 registration at door). Hardcopy of workshop presentations, lunch and refreshments included.

Topics:

IND/CTA Overview

- Janice Mallison, Regulatory Affairs Consultant, Regulatory and Drug Development Consulting.

Chemistry, Manufacturing & Controls

- Tracy Meffen, Vice President, Quality & Regulatory Affairs, Genevant Sciences.

Pharmacology, Drug Metabolism and Pharmacokinetics

- Greg Loewen, Director of Technical Support at SEKISUI XenoTech.
- Dr. Harvey Wong, Associate Professor of Pharmacokinetics, University of British Columbia

About the Workshop and Who should attend:

- Knowing the objectives, expectations, and processes of assembling and filing an IND or CTA is the key to not only a successful filing but also a promising clinical development path forward. Often, there are cases where too many nice-to-have studies crowd in the package but critical studies/issues are not addressed, and this can lead to significant delays in clinical development.
- Our speakers are highly experienced with regulatory filings and will discuss systematically the product development strategy for small molecule and biologics filings and the nuts, bolts, and best practices for putting together a high-quality submission package, as well as how to interact with various regulatory agencies.
- The Workshop is separated into two parts both of which are aimed at those working in academic and industry, who are wishing to learn about different aspects of preclinical requirements in drug development, or those who wish to upgrade or broaden their current skills in preclinical and clinical research and development, regulatory affairs, and drug safety in general.