

CDRD Training Program: Drug Development Workshop #7

CDRD is pleased to offer the following training session as part of the workshop component of the CDRD Training Program:

<i>Title:</i>	Clinical Drug Development – Evaluating the Safety and Efficacy of Drugs in Humans
<i>Presenter:</i>	Larry S. Gontovnick, Ph.D.
<i>Date:</i>	Thursday, November 25, 2010
<i>Time:</i>	1:00 pm – 4:30pm <i>(Refreshments served at 12:45pm, and workshop begins at 1 :00 pm sharp.)</i>
<i>Location:</i>	Life Sciences Institute, Room 1510, UBC Campus
<i>Seats Available:</i>	Limited seating.

Workshop Overview:

This workshop will review the phases of clinical drug development and the objectives of clinical trials within each phase. Discussion will focus on the design and conduct of clinical trials to meet the scientific, medical and regulatory requirements for global drug approval and commercialization.

Learning Objectives:

- Differentiate between Phase I, II, III and IV clinical development; provide the rationale , key considerations and potential challenges for each phase
- Describe the basic concepts of clinical research including trial designs, protocol development, patient enrolment and trial conduct
- Discuss how pharmacokinetic, pharmacoeconomic, drug interaction and special population studies fit into the clinical development process
- Describe the role of clinical trials in the post-marketing period

Workshop Content:

- Where clinical drug development fits into the drug development process
- Phases of clinical drug development – objectives and challenges of each phase
- Interactions with regulatory agencies during clinical drug development (from pre-IND to pre-NDA meetings)
- Study designs – dose escalation, double-blind, crossover, adaptive, etc.
- Pharmacokinetic, pharmacogenomic, pharmacoeconomic, drug interaction and special population studies
- Clinical trial protocol – patient selection criteria, assessments, endpoints, sample size, statistical analysis, adverse event reporting and other key protocol sections
- Regulations that apply – refresh on informed consent, proper documentation and other key elements of GCP
- Clinical trial conduct – the challenges in running a successful clinical trial
- Clinical development roles – Study Director, Study Manager, Clinical Research Associate, etc.

Expert Presenter's Biography:

Dr. Gontovnick is Vice President, Research and Development at WEX Pharmaceuticals in Vancouver. He oversees the clinical development of WEX's lead product (Tetrodotoxin-TTX) for chronic cancer-related pain and for prolonged local anaesthesia.

Dr. Gontovnick has over 25 years of experience in drug development in biotech and big pharma. He was Vice President, Drug Development at Twinstrand Therapeutics (2003-2008) and Vice President, Clinical Development and Regulatory Affairs at Cipher Pharmaceuticals (2002-2003), where he was responsible for the clinical programs and regulatory filings for several novel investigational drug products. He was Senior Director, Clinical Development at GlaxoSmithKline (1992-2001), where he led a department of 150 scientific and administrative staff that represented Canada on global clinical development teams and was responsible for the conduct of international and local clinical trials in Canada. He also served as Head, Clinical Investigation at CIBA-Geigy Canada (1985-1992), where he was a member of the international development team for formoterol, a long-acting inhaled β_2 -agonist.

Dr. Gontovnick received his Ph.D. degree in pharmacology from the University of British Columbia where he was a graduate student in the Faculty of Pharmaceutical Sciences. He was a Medical Research Council of Canada Postdoctoral Fellow at the University of Wisconsin's McArdle Laboratory for Cancer Research and an Edward Christie Stevens Postdoctoral Fellow at the Ontario Cancer Institute. He was an Assistant Professor (part-time) at the Faculty of Health Sciences, McMaster University (1992-1995) and a Visiting Assistant Professor at the Faculty of Pharmaceutical Sciences, University of British Columbia (1988). He is a member of the Canadian Society of Pharmacology and Therapeutics.

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