

Profile for Kory J. Engelke, PhD, DABT:

After completing his doctorate in Pharmacology from the University of Vermont, College of Medicine, in which he elucidated the pharmacological and toxicological properties of novel anti-cancer drugs, Dr. Engelke was awarded a University Post Doctoral Fellowship at The Ohio State University to further his work into the toxicity of anti-cancer drugs.

After completing this project, Dr. Engelke took a position as a study director at Battelle Memorial Institute. In addition to his study director responsibilities, he participated as the toxicologist on the interdisciplinary team which was responsible for the successful compilation and defense of Battelle's first IND (a clinical indication to treat lung cancer by inhalation therapy).

Dr. Engelke subsequently accepted a position at Guilford Pharmaceuticals where he was a member of several multidisciplinary development teams and successfully designed and monitored IND-enabling studies. While at Guilford, Dr. Engelke successfully co-authored and defended an IND utilizing microspheres as a novel therapy of lung cancer and ovarian cancer; he also co-authored/defended Phase II packages for several other proprietary compounds in Guilford's pipeline. In addition, he was the toxicology representative on the multidisciplinary team working on the flagship compound (an anesthetic) which, due to metabolism concerns, allowed Dr. Engelke to participate in the preparation of several position papers. Moreover, he defended these positions to both management and world-wide regulatory bodies, thus enabling Guilford to move forward into Phase I and II studies in the US and start studies in Europe.

Subsequent to his success at Guilford, Dr. Engelke accepted a position at Sucampo Pharmaceuticals where he managed the entire preclinical department. In addition to designing, conducting and monitoring the preclinical studies to define the efficacy, pharmacokinetic and safety profiles of all candidate compounds, he also planned, compiled, presented and/or defended all preclinical regulatory submissions and position papers for these compounds. Furthermore, although there was much debate with the various world wide regulatory agencies in regards to the potential safety profile of Sucampo's principal compound (for the treatment of chronic constipation), Dr. Engelke designed the strategy which successfully addressed these apprehensions thus permitting the marketing of AMITIZA™ (lubiprostone capsules) with a favorable label in the US.

After the acceptance of AMITIZA™ and with his experience effectively progressing drug candidates from chemist's bench to market, Dr. Engelke accepted a position at a preclinical contract research organization to further expand his preclinical knowledge and experience by performing various types of studies with diverse study designs. In this capacity, Dr. Engelke has been study director on over 75 studies for a variety of clinical indications and works closely with several of the largest clients of the company, including the government.

Dr. Engelke launched Product Development Services at AVANZA Laboratories. This expanded offering by AVANZA will provide advice and assistance for virtual to small sized pharmaceutical/biotechnology companies in the areas of drug optimization, preclinical evaluation, and safety assessment to support the conduct of clinical trials and drug registration.

Dr. Engelke is a Diplomate of the American Board of Toxicology and is a member of both the Society of Toxicology and American College of Toxicology.