



American Society for Quality (www.asq.org) – Washington DC and Maryland Metro, Section 509 (www.asq509.org)

Biomed/Biotech Special Interest Group (SIG) Meeting
(<http://www.asq509.org/ht/d/sp/i/31557/pid/31557>)

Preclinical Development for Drugs, Biologics, and Medical Devices – A Pathologist’s Perspective

To be presented by

William Iverson, DVM, DACVP
Senior Pathologist, MedImmune, LLC
(IversonW@MedImmune.com)

Thursday, September 24, 2015

6:00 – 6:20 PM – Networking; Pizza/drink

6:20 – 8:45 PM – Program

8:45 – 9:00 PM – Door-prizes drawing; Networking

Online Registration site: <http://www.asq509.org/ht/d/DoSurvey/i/35817>

Open to Public –

\$5: non-ASQ members to cover pizza/drink cost;

Free: ASQ members, veterans, senior citizens, past speakers, US PHS Commissioned Corp officers, teachers, students, interns, residents, postdocs, FDA Commissioner’s Fellows, MJ-DC members, NTUAADC members, CAPA members, CKUAADC members, CCACC volunteers/employees, FAPAC members, CBA members, AAGEN members, and current job-seekers

Location: Kelly’s Deli Conference Center, 7529 Standish Place, Rockville (Derwood, for GPS users), MD 20855

Registration Deadline: Please register by Thursday noon, September 24, 2015.

Question: Please contact Dr. C.J. George Chang, Chair of Biomed/Biotech SIG, ASQ509; gchang2008@yahoo.com or 240-793-8425 (cell).

Driving directions: By Cars: From I-270 (N or S bound): Take Exit 9A and exit from the FIRST right exit; turn left (east) onto Shady Grove Dr.; turn right (south) onto Rockville Pike (**Route 355**); turn left (east) onto East Gude Dr.; turn left (north) immediately onto Crabb’s Branch Dr.; turn left (west) immediately onto Standish Place. The first building on your right side is 7519 Standish Place; open parking). The venue is on the first floor of 7529 Building with its external entrance opposite to the left side of 7519 building main entrance. **By Metro trains:** Off from Red Line **Shady Grove Station**, and take RideOn **Route 59 TOWARD ROCKVILLE** and get off from “**Calhoun Place**” stop. Standish Place is next to the Bus stop. Our venue is within 2 min of walking distance from the stop.

Summary

Non-clinical studies in an animal model(s) are normally required by most regulatory authorities before a new molecule can be administered to humans. This presentation will describe what typical studies are required for both small and large molecules from the first dose in human, through the development cycle to a marketing application. It will include a description of what in vitro and in vivo studies are required to assess genotoxicity, potential adverse pharmacology, organ toxicity, reproductive effects, and carcinogenicity.

A brief discussion of pharmacodynamics and pharmacokinetics and their importance in establishing safety margins will also be included. Focus will be on what data are collected in all of these studies, especially with regard to anatomic and clinical pathology. All studies to support safety must be performed under GLP regulations, and ICH has been a great help to harmonize requirements internationally.

Speaker's Bio: William Iverson, DVM, Diplomate ACVP

Dr. William Iverson is a native of Chicago and received undergraduate and veterinary training at Purdue University, W. Lafayette, Indiana. Following three years clinical work in a mixed (large and small animal) practice in Florida, he was accepted as a **resident** at the University of Florida's new College of Veterinary Medicine and completed three years training in comparative pathology and was then certified by the American College of Veterinary Pathology (ACVP).

He then began working at Experimental Pathology Laboratories in Sterling, VA, which was the first pathology CRO founded specifically to support the toxicology field. After six years he joined Ciba-Geigy Pharmaceutical Company, one of the predecessor companies to form Novartis, in Summit, NJ, as **Director of Pathology**.

In 1991 he joined Sandoz Pharmaceutical Company, the other predecessor company, and continued in pathology until 1997 when he assumed management of all the Novartis New Jersey animal facilities as **Attending Veterinarian**. He left Novartis in 2006 to relocate to rural Virginia and has worked at MedImmune, LLC since 2009 as a **Senior Pathologist**. While at Novartis Bill also served on drug development teams, representing toxicology, and helped bring 7 NCEs to market.

Bill's wife, Ann, lives on the farm during the week with their retired Beagle, Gracie. Bill's daughter Sally Ann, DVM, MPH, is a Veterinary Medical Officer (VMO) with USDA, APHIS, FADDL and works in the research facility on Plum Island, New York.

This Biomed/Biotech SIG event is cosponsored by the Monte Jade Science and Technology Association of Greater Washington (www.MonteJadeDC.org) and NTU Alumni Association at DC (www.ntuaadc.org).