



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>)

“2016 ICH E6(R2) Good Clinical Practice Addendum - Impact on Quality and Clinical CRO Operations”

To be presented by

Jan Peterson, MS
(jpeterson@emmes.com)
Senior Regulatory Affairs Manager
Emmes Corporation, Rockville, MD

Thursday, May 18, 2017

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

6:20 – 8:45 PM – Program

8:45 – 8:55 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, NTMUADC members, CKUAADC members, NTHUAADC members, NJTUAADC members, CCACC volunteers/employees, FAPAC members, CBA members, AAGEN members, NCARSQA members, OCA-DC members, AAMB members, ACAP members, DC Leaders Club members, BioTrain volunteers, 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, May 18, 2017](#).

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

Good Clinical Practice (GCP)—and we must read this as “Good Clinical *Research* Practice” — and quality in clinical research were always expected to go hand-in-hand. But until the recent update to the 20-year-old international GCP Guidelines, which were adopted as “guidance” by FDA in 1996 in lieu of regulations proposed earlier, quality systems approaches and risk-based methodologies were not widely recommended or utilized in either academic- or industry-sponsored clinical trials. The new “E6(R2)” Guideline update changes that, emphasizing both aspects so that many consider this a significant change to the management approach and operational conduct of clinical research. We’ll discuss key changes to the GCP Guideline and the impact they may have on data managers, quality monitors, and auditors for sponsors and the clinical research organizations (CROs) they hire to manage clinical trials.

Speaker’s Bio: Jan Peterson, MS



Mr. Peterson’s early career was based in academic settings at the University of Minnesota and the University of California at San Francisco, conducting both preclinical and clinical work in neurophysiology and ocular pharmacology research. He completed his MS degree in Pharmacology and Experimental Therapeutics at UCSF, and accumulated extensive experience in basic pharmacology, physiology, and clinical research in settings including neurosurgical treatments for injury and pain, studies involving cardiology, diabetes, urology, immunology, ocular pharmacology, retinal degenerative conditions, and surgical interventions for glaucoma and refractive errors. So while he has always loved working in a variety of clinical and regulated product areas over the past 40+ years (and mastering none, for sure, especially during those years doing device manufacturing SWAT team inspections), he considers clinical vision research as “home base.” He has been a volunteer on industry-FDA standards development committees since 2004, including an American National Standards Institute (ANSI) Z80 committee for ophthalmic medical devices, and has personally directed and monitored multi-national trials for the successful FDA and CE mark approval of ophthalmic laser products for both refractive surgery and glaucoma, and an implanted ocular device for glaucoma.

Mr. Peterson is the **Vice-Chair** of the Association of Clinical Research Professionals (ACRP) Regulatory Affairs Committee and a contributing Item **Writer** to the Academy of Clinical Research Professionals Global CCRA and ACRP-Certified Professional Certification Exam committees. He is Regulatory Affairs Certified (RAC-US) by the Regulatory Affairs Professionals Society (RAPS), a Senior Member of the American Society for Quality (ASQ) and an ASQ Certified Biomedical Auditor (CBA). He has prepared or contributed to numerous successful clinical trial applications (CTAs) for INDs and IDEs from the US FDA, Health Canada, and Israel, as well as successful 510(k), PMA, and NDA marketing applications in the United States.

He has developed strong professional relationships with FDA regulators for drug, biologic, and medical device applications, and participated and presented at client-FDA meetings and FDA Advisory Panel meetings. Since 1999 he has been employed at a CRO called the Emmes Corporation in Rockville, a growing, private CRO with now over 550 people (owned and run by biostatisticians) whose mission is focused on supporting clinical research trials for government, academic and industry sponsors to generate and disseminate quality clinical research information to benefit the public health. Mr. Peterson would love to travel more but mostly flies a desk now helping various projects navigate the regulatory requirements for their clinical trials as a **Senior Regulatory Affairs Manager** at Emmes.

This event is cosponsored by NTU Alumni Association DC Chapter (www.ntuaadc.org) and Chinese American Professional Association DC Chapter (www.capadc.org).