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)

"Good Clinical Practice in the United States"

To be presented by

Martin Rose, MD, JD

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Medical Officer and Clinical Team Leader
Division of Cardiovascular and Renal Products
Office of New Drugs
Center for Drug Evaluation and Review (CDER), US FDA

Thursday, February 8, 2018

[New venue**: CCACC, 9318 Gaither Rd. Suite 215, Gaithersburg, MD]**

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, current job-seekers, CCACC volunteers/employees/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, FAPAC members, CBA members, AAGEN members, NCARSQA members, OCA-DC members, AAMB members, ACAP members, DC Leaders Club members, BioTrain volunteers, and Tai-Chi classes students in Metropolitan DC.

Location (New Venue**): CCACC 9318 Suite 215, Gaither Rd., Gaithersburg, MD20877**

Registration Deadline: Please register by ***Thursday noon, February 8,*** *2018.*
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 8 onto Shady Grove Dr. Drive toward east and turn left onto Gaither Rd. The building is on your left after passing a stop sign.
By Metro rail: Exit at the Red Line Shady Grove Station.

Summary

Good clinical practice (GCP) has evolved substantially since its birth in the post-World War II era. My presentation will briefly describe the tragic events that led to development of GCP. We will then discuss current GCP in the US, as described in FDA's GCP guidance and related guidance. The obligations of research sponsors, investigators and IRBs will be stressed, as well as recent developments in the application of GCP to clinical research at FDA.

Speaker's Bio: Martin Rose, MD, JD

Dr. Martin Rose is a graduate of the University of California, San Francisco, School of Medicine with subsequent training in Internal Medicine and Endocrinology. He also obtained a law degree from the University of California, Berkeley.

Dr. Rose's professional experience includes over 20 years in the pharmaceutical industry in various positions as well as 11 years in the Division of Cardiovascular and Renal Products in FDA's Office of New Drugs. He currently serves as a **Clinical Team Leader** in the Division.

This event is cosponsored by Chinese Culture and Community Service Center, Inc. (CCACC, www.ccacc-dc.org), NTU Alumni Association DC Chapter (www.ntuaadc.org), and Chinese American Professional Association of Metropolitan Washington, DC (www.capadc.org).

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