



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>)

“Comparison of US-China Regulatory Systems”

To be presented by

Dan Zhang, MD, MPH, MS
(dan.zhang@fountain-med.com)
Executive Chairman
Fountain Medical Development Ltd.

Thursday, May 3, 2018

****New venue**:** **CCACC HQ, 9366 Gaither Rd. “1st Floor Music Room”,
Gaithersburg, MD 20877**

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

6:20 – 8:50 PM – Program

8:50 – 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, 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 all Tai-Chi classes students in Metropolitan DC.

Registration Deadline: Please register by ***Thursday noon, May 3, 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

China Food and Drug Administration (CFDA) experienced an unprecedented change in last 2.5 years in terms of regulatory system. It also became an ICH member last June. These changes have produced dramatic impact on global development planning and implementations, considering China now is the second largest pharmaceutical market after US. This presentation will highlight aggregated regulatory changes in China, major differences between FDA and CFDA's regulatory process, and implied impact on the efficiency of drug development process.

Speaker

Dr. Dan Zhang is the **Executive Chairman** of Fountain Medical Development Ltd, a clinical CRO with 1700 employees operating in China, Hong Kong, Taiwan, South Korea, Japan, UK, India, Philippines, Armenia & USA. Dr. Zhang was the **Head** of Clinical Development and was the **Head** of Safety Assessment at Sigma-Tau Research Inc. - leading Italian Pharmaceutical Company, He was the **vice president** at the Quintiles Transnational Corp., the world largest clinical CRO, and **Chairman** of Quintiles Medical Development (Shanghai) Company Ltd.,



Dr. Zhang is a **member** of grant review committee for National Drug Development Fund of China, and is also a **consultant** for the CFDA. He is a **member** of ICH E19 Expert Working Group. He is also chairing the committee of Pharmaceutical R&D, China Pharmaceutical Industry Research and Development Association. Dr. Zhang is also a **senior consultant** for the Chinese Academy of Medical Sciences and Peking Union Medical College. He was a **member** of the Overseas Expert Committee on New Drug R&D for the Ministry of Science and Technology of China, and was the **secretary-general** of the Association of "Thousand Talent" Expert from 2011-2017. Dr. Zhang was the former board of directors for the Sino-American Pharmaceutical Association (SAPA) and was the former **president** of Chinese Biopharmaceutical Association-USA (CBA). Dr. Zhang is chairing the government relationship committee of Bayhelix - an organization hosting senior executives from life-science organizations in USA and China.

Dr. Zhang received his pre-med training from Peking University and received M.D. from Peking Union Medical College. He then went to the Harvard School of Public Health and received MPH in health policy and management. Then he went to the Wharton Business School of the University of Pennsylvania, where he obtained his master's degree in healthcare management in 1998.

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 Professionals Association of Metropolitan Washington, DC (www.capadc.org).

