



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

Biomed/Biotech Special Interest Group (SIG) Meeting

“Medical Device Development - Underpinning by Quality System”

Presented by

David West, PhD, MPH
Vice President, Quintiles Consulting

Thursday, November 18, 2010

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

6:20 – 8:30 PM – Program (a 10-min break at 7:40 pm)

8:30 – 8:45 PM – Door-prizes drawing; Networking

Open to Public - Free to [ASQ Members](#) (*Become a ASQ Member & Save*)
\$5 for [non-ASQ members](#) to cover pizza/drink cost
Free to all Local [High/Middle/Elementary School Students, interns,](#)
[and FDA Commisioner’s Fellows](#)

Location: Kelly’s Deli Conference Center, 7519 Standish Place, Rockville, MD 20855

Registration Deadline: For headcount purpose, please register by *Thursday noon, November 18, 2010.*

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

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

Presentation Summary: “Medical Device Development – Underpinning by Quality System”

Dr. West plans to present and lead our discussion about the following:

- **Axiom:** poorly conceived, planned, or implemented device development efforts will result in project failure or waste time and money

– **Device development underpinning by quality system**

A discussion of the role of Design Controls per Quality System Regulation (QSR) in the development of novel medical devices

– **Case studies**

- Combination product for combined treatment
- Combination product for drug delivery
- Extracorporeal blood treatment device
- Automated therapeutic device for home use
- Ablation catheter for cardiac arrhythmias

Speaker Biography: David West, PhD, MPH
(david.west@quintiles.com)

As a **Vice President of Quintiles Consulting**, Dr. West assists domestic and international medical device companies to develop and implement strategic and regulatory plans for medical devices and combination products. Since 1994, he has been providing clients strategic and regulatory support throughout the product development and regulatory approval processes, identifying and reviewing both pre-clinical and clinical studies, and offering expert assistance in the preparation of IDE, PMA, PDP, and 510(k) applications. Dr. West offers clients the benefit of 26 years of service as a **Commissioned Officer in the US Public Health Service**, including 11 years in senior management positions at the Food and Drug Administration (FDA).

From 1985 to 1989, Dr. West was the **Associate Director, Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH), FDA**. From 1989 to 1993, he was **Deputy Director of ODE**. In these two positions he was responsible for planning, managing, and directing programs to ensure the safety and effectiveness of medical devices, including extensive review of IDE, PMA and 510(k) applications. During his tenure in these two positions, he exercised final FDA review and signature authority for virtually all IDE and PMA applications, and for precedent-setting, complex or potentially controversial 510(k)s. Dr. West was a principal architect of the decision framework for FDA's evaluation and regulation of combination products of medical devices, drugs, and/or biologics and served on FDA's first **Combination Products Task Force**.

Dr. West earned his PhD in Environmental Health (major) and Epidemiology (minor) at the University of Minnesota; his MPH at the School of Public Health, University of Minnesota; and his BS in Mechanical Engineering at the University of California, Santa Barbara.

Directions to meeting: From I-270 (North or South bound):

Take Exit 9A and exit from the first right exit.

Turn left (east) onto Shady Grove Drive.

Turn right (south) onto Rockville Pike (**Route 355**).

Turn left (east) onto East Gude Drive.

Turn left (north) immediately onto Crabbs Branch Drive.

Turn left (west) immediately onto Standish Place.

The first building on your right side is 7519 Standish Place; open parking. The conference room is on the first floor with its entrance opposite to the left side of 7519 building main entrance.