



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

## Biomed/Biotech Special Interest Group Meeting

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### **“Why Quality by Design (QbD) - A Case Study”**

Presented by

**Raafat Fahmy, PhD**

Science Advisor, Div. Manufacturing Technologies  
Office of New Animal Drug Evaluation  
Centers for Veterinary Medicine, FDA

### **January 28 (Thursday) Evening**

6:00 PM – Networking and Pizza and soft drink with a door prize

**6:20 – 8:50 PM** – Program (a break at 7:30 pm)

8:50 – 9:00 PM – Door-prize drawing and networking

*Open and free to the public*

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#### **Location:**

**Kelly's Deli Conference Center**, 7519 Standish Place, Rockville, MD 20855

#### **Driving directions:**

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 conference room is on the first floor with its entrance opposite to the left side of building main entrance.

**For headcount purpose, please register by Thursday noon, January 28, 2010.**

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

For registration problems or further information contact **Dr. George Chang**, Co-Chair of Biomed/Biotech SIG, at [gchang2008@yahoo.com](mailto:gchang2008@yahoo.com) or call **240-793-8425**.

#### **Presentation Summary:**

##### **Why Quality by Design? A Case Study.**

Quality by design (QbD) is the FDA's latest initiative to encourage the industries to improve product quality and to potentially reduce regulatory operation costs. The QbD process incorporates quality into the product by carefully evaluating all critical quality attributes from the early stages of development and throughout the products lifecycle. QbD is part of a broader FDA initiative, Pharmaceutical Quality for the 21<sup>st</sup> Century: A Risk-

based Approach. Ultimately, QbD allows one to build quality into a product with a thorough understanding of potential manufacturing variables, the management of potential risks to product quality and performance, and the establishment of processes to mitigate the identified risks. The degree of regulatory flexibility depends on the manufacturer's demonstrated level of product and process understanding and controls used in the implementation of a modern quality system. In this presentation, Dr. Fahmy plans to discuss how we can apply the concept of QbD during the development of any pharmaceutical dosage form and presenting a case study. QbD can be implemented to many different types of the operations in our daily lives and work.

## **Speakers' Bios:**

### **Raafat Fahmy, PhD ([raafat.fahmy@fda.hhs.gov](mailto:raafat.fahmy@fda.hhs.gov))**

Dr. Fahmy has over twenty-one years of experience in the pharmaceutical industry. For the past decade, Dr. Fahmy have served as a regulatory scientist/science advisor at the FDA and collaborated with the academia in several research programs. He provides leadership in the areas of drug product formulation, manufacturing and technology, including the evolving field of dissolution, formulations, manufacturing, and chemometrics. He also works with other experts at the agency and other organizations to provide scientific expertise in the development of policies and guidances in the area of manufacturing processes. He often represents FDA/CVM on manufacturing issues in national and international scientific symposiums; his critical path research supports innovation and efficiency in pharmaceutical development, manufacturing, and quality control. His collaborative research projects with the University of MD School of Pharmacy enhances manufacturing science, improves the scientific basis for understanding the behavior of pharmaceutical materials, and allows for the development of robust processes early in the development process. Dr. Fahmy has also authored several textbook chapters, articles, and scientific papers, and commonly consulted by various review in CDER, FDA and compliance groups in regard to reviewing process analytical technology (PAT) and QbD applications.

Dr. Fahmy was the chairperson for the Committee of Advancement FDA Science (CAFDAS) in 2006. Most recently, he chaired the QbD session at the Controlled Release Society annual meeting. Copenhagen, Denmark, July, 2009, and organized/chaired the QbD workshop for the Animal Health Industry, October, 2009, Alexandria, VA. He is currently a member of the USP Veterinary Biopharmaceutics Classification System *Ad Hoc* Advisory panel.