



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

---

# “Generic Drugs: Myths and Facts”

Presented by

**Lawrence X. Yu, MS, PhD**

([lawrence.yu@fda.hhs.gov](mailto:lawrence.yu@fda.hhs.gov))

**Director for Science**

Office of Generic Drugs (OGD)

Center for Drugs Evaluation and Review (CDER), FDA

**July 30, 2009 (Thursday) Evening**

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

**6:20 – 8:20 PM – Program**

**8:20 – 8:40 PM – Door-prize drawing and networking**

***Open and free to the public***

---

### 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, July 30, 2009.**

**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**.

## 7/30/09 Event Speaker' Bios:

### Lawrence X. Yu, MS, PhD

Dr. Lawrence X. Yu is the Director for Science at the Office of Generic Drugs (OGD), Food and Drug Administration. He is also adjunct Professor of Pharmaceutical Engineering at the University of Michigan and adjunct associate Professor of Pharmaceutical Sciences at the University of Maryland. Prior to joining the FDA, Dr. Yu had worked at Pfizer (Upjohn) and GlaxoWellcome for 8 years. Dr. Yu joined the FDA in 1999 and has served as Team Leader, Deputy Division Director, and Division Director.

Dr. Yu's research interests have centered on the prediction of oral drug delivery and the development of pharmaceutical Quality by Design. His compartmental absorption and transit (CAT) model has laid the foundation for the commercial software, GastroPLUS™ and Simcyp®, which are being widely used in the pharmaceutical industry. Dr. Yu is a fellow and the Section Chair of the American Association of Pharmaceutical Scientists (AAPS) and an Associate Editor of the AAPS Journal. Dr. Yu has authored/co-authored over 150 papers, book chapters, and abstracts, and given over 120 invited presentations. He is a co-editor of the book entitled "*Biopharmaceutics Applications in Drug Development*". Dr. Yu is also the winner of numerous awards including the American Foundation for Pharmaceutical Education Fellowship, AAPS Excellent Graduate Research, Department of Health and Human Service Outstanding Leadership Award, FDA Commissioner's Special Citation, Outstanding Achievement, Group Recognition, Regulatory Science, and Team Excellence awards, Upjohn special recognition award, and Naigai Foundation Japan Tokyo Distinguished Lectureship.

Dr. Yu received his B.S. in Chemical Engineering from Zhejiang Institute of Technology, his 1<sup>st</sup> M.S. in Chemical Engineering from Zhejiang University and 2<sup>nd</sup> M.S. in Pharmaceutics from the University of Cincinnati, and his Ph.D. in Pharmaceutics from the University of Michigan.