華美化學與化工學會
Chinese-American Chemical Society (CACS)

2017 Fall Meeting and Banquet

At the ACS Fall National Meeting
August 21st, 2017, Washington, DC, USA
Registration Fee: $40/person. On-site registration available

Monday, August 21st, 2017

6:30 pm -- 7:30 pm	Registration and Social Hour
7:30 pm -- 8:15 pm	Dinner Banquet
8:15 pm -- 8:30 pm	Welcome and Introductory Remarks **Dr. Marinda Li WU, CACS Board, ACS Past President**
8:30 pm -- 8:45 pm	Introduction of Special Guests, Sponsors, and other guests **Dr. Marinda Li WU**
8:45 pm -- 9:00 pm	Introduction of Keynote Speaker, Dr. Lawrence Yu **Dr. Baoqing MA, President of Tri-State CACS Chapter**
9:00 pm -- 10:00 pm	Keynote Address: **Evolution of FDA Pharmaceutical Quality Oversight** **Dr. Lawrence YU, Deputy Director, Office of Pharmaceutical Quality, FDA**
10:00 pm -- 10:15 pm	Announcement of Job Openings and Concluding Remarks **Dr. Marinda Li WU**

Tony Cheng's Seafood Restaurant
619 H St NW, Washington, DC 20001
Phone: (202) 371-8669

Thanks to our sponsor:

药明康德 WuXi AppTec

華美化學與化工學會
Chinese-American Chemical Society (CACS)

2017 Fall Meeting and Banquet

August 21st, 2017, Washington, DC, USA

****

Keynote Address:

Evolution of FDA Pharmaceutical Quality Oversight

Dr. Lawrence YU

Deputy Director, Office of Pharmaceutical Quality, Food and Drug Administration, USA

Abstract

The launch of the Center for Drug Evaluation and Research (CDER) Office of Pharmaceutical Quality (OPQ) is a milestone in FDA's efforts to assure that quality medicines are available to the American public. As a new super-office within CDER, OPQ is strategically organized to streamline regulatory processes, advance regulatory standards, align areas of expertise, and originate surveillance of drug quality. Supporting these objectives will be an innovative and systematic approach to product quality knowledge management and informatics. Concerted strategies will bring parity to the oversight of innovator and generic drugs as well as domestic and international facilities. OPQ will promote and encourage the adoption of emerging pharmaceutical technology to enhance pharmaceutical quality and potentially reinvigorate the pharmaceutical manufacturing sector in the United States. With a motto of "One Quality Voice," OPQ embodies the closer integration of review, inspection, surveillance, policy, and research for the purpose of strengthening pharmaceutical quality on a global scale.

Tony Cheng's Seafood Restaurant

619 H St NW, Washington, DC 20001

Phone: (202) 371-8669

Biography

Lawrence X. Yu, Ph.D., is the Deputy Director, Office of Pharmaceutical Quality, Food and Drug Administration, where he oversees new, generic, and biotechnology product quality review and inspection functions as well as the FDA CDER quality labs. He is also adjunct Professor of Pharmaceutical Engineering at the University of Michigan.

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, Division Director, Deputy Office Director, and Office 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, GastroPLUSTM and Simcyp®, which are being widely used in the pharmaceutical industry. Dr. Yu is a fellow and the past section Chair of the American Association of Pharmaceutical Scientists and an Associate Editor of the AAPS Journal.

Dr. Yu has authored/co-authored over 130 papers, and presented over 100 abstracts, and given over 200 invited presentations. He is a co-editor of the books entitled "Biopharmaceutics Applications in Drug Development", "FDA Bioequivalence Standards", and "Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice, 2nd Ed." Dr. Yu is the winner of numerous awards including AAPS Regulatory Science Achievement award, AIChE PD2M Drug Product QbD Achievement Award, Japan Naigai Foundation Distinguished Lectureship, China Beijing University IPEM graduation commencement address, Department of Health and Human Service Outstanding Leadership Award, FDA Commissioner's Special Citation, Outstanding Achievement, Group Recognition, and Team Excellence awards.

Tony Cheng's Seafood Restaurant

619 H St NW, Washington, DC 20001

Phone: (202) 371-8669