DEPARTMENT OF CHEMISTRY AND ENVIRONMENTAL SCIENCE SEMINAR SERIES SPRING 2019

DATE: TUESDAY, APRIL 30, 2019 LOCATION: Central King Bldg. - 303 TIME: 1:00pm – 2:20pm

GUEST SPEAKER

Xiaoyi Gong, Ph.D.

Director, Analytical Chemistry Merck Manufacturing Division of Merck Sharp and Dohme Corp (MSD)

TOPIC

Emerging Needs in Pharmaceutical Research, Development and Commercialization – the Challenges, and Opportunities to Analytical Chemistry

ABSTRACT

Advance of analytical chemistry has played a central role in driving discovery, development and manufacturing of novel medicines. Modern analytical tools including chromatography, spectroscopy, NMR, mass spectrometry have become essential today to pharmaceutical research, development and commercialization. In the last decade, new challenges have emerged in the pharmaceutical industry, due to evolving global biomedical needs, innovation in science and technologies, as well as the rapidly changing business and regulatory environment. These challenges have created new applications that demand improved analytical tools that can offer faster speed, higher resolution, and better sensitivity, as well as novel analytical techniques that can enable us to perform measurements that have not been possible to date. In many cases, these new applications have been under recognized or even misunderstood by the researchers and technology vendors in the field of analytical chemistry. In this presentation, some of these new applications and the opportunities to analytical chemistry will be explained in the context of pharmaceutical research, development and commercialization, with the call for attention of the academia and technology vendors to invest in research to meet these new challenges to analytical chemistry.

<u>BIO</u>

Xiaoyi Gong is Director of Analytical Chemistry in Merck Manufacturing Division of Merck Sharp and Dohme Corp. (MSD). He leads a team of analytical chemists supporting development, registration and commercialization of novel drug products. He is a recognized expert of international regulatory guidelines for pharmaceutical development. Currently he serves as the chair of the Working Group of ICH Q3D Guideline for Elemental Impurities for International Consortium for Innovation & Quality in Pharmaceutical Development (IQ), and is member of multiple drug development oversight committees internally at Merck.

Xiaoyi is also a leading expert of new analytical technologies in the pharmaceutical industry. He has led multiple technical groups focusing on applying state-of-art analytical techniques for analytical method screening and development, high-throughput analysis, elemental analysis, labelled compound analysis, and structural characterization of metabolites. He pioneered development and implementation of a number of new analytical technologies across these fields.

He chaired the Analytical Workgroup of the New Technologies Review & Licensing Committee at Merck that coordinates acquisition, evaluation, and implementation of new analytical technologies for the global Merck organization.

Xiaoyi obtained a Ph.D. in Analytical Chemistry from Iowa State University in 2000. His research interests are in modern analytical instrumentation, detection techniques, separation science, chirality, high-throughput analysis, and elemental analysis. In addition to over 50 publications in peer reviewed scientific journals and multiple patents, Xiaoyi has been recognized with the following distinctions: R&D 100 Award (2000); Inventors Award, Iowa State University (2011); Merck Presidential Award for Green Chemistry (2011) for promoting SFC technologies at Merck; Special Achievement Awards, Merck Research Laboratories (2012, 2014) for championing new analytical technology evaluation and implementation, and global deployment of next generation HPLC technology at Merck.