IOWA STATE UNIVERSITY
Department of Chemical and Biological Engineering

Graduate Seminar Series 2017-18

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Office of Pharmaceutical Quality (OPQ),
Office of Process and Facilities (OPF),
Center for Drug Evaluation and Research (CDER)**

US Food and Drug Administration

Silver Spring, MD

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11:00 a.m.

171 Durham Center

Iowa State University

Frontiers of Modern Pharmaceutical Manufacturing: Process Analytical Technology (PAT), Continuous Manufacturing, and Advanced Manufacturing Control

In the past decade, the pharmaceutical sector has been experiencing a lot of changes, from discovery, development, to manufacturing. Traditionally pharmaceutical manufacturing has been dominated by batch processing, which inherently presents certain challenges to the manufacturing efficiency, product quality, and process control. As a major pharmaceutical quality initiative in the 21st Century, the US Food and Drug Administration (FDA) has encouraged the pharmaceutical industry to adopt innovation and advanced manufacturing technologies such as Process Analytical Technology (PAT), Continuous Manufacturing (CM), and Advanced Manufacturing Control. In this presentation, the basic concepts of PAT, CM, and Advanced Manufacturing Control will be introduced briefly. Some case studies based on FDA research and published results will be used to illustrate how chemical engineering can make vital contributions to advance pharmaceutical manufacturing and benefit the public health. Some of the challenges and opportunities during the journey of modernizing pharmaceutical manufacturing will be discussed from technical, engineering, and regulatory science perspectives.

Huiquan Wu received his B.S. from Wuhan Institute of Technology in 1985, his M.S. from Sichuan University in 1988, and his Ph.D. from Iowa State University (all in chemical engineering), with a minor in materials science and engineering from Iowa State in 2001. He worked for LSI Logic (Santa Clara, CA) and ACM Research (Fremont, CA) as a senior process engineer and then joined the Center for Drug Evaluation and Research (CDER), US Food and Drug Administration (FDA). He has worked at various positions across various functions within CDER, including policy development, research, and regulatory science reviewer. He was promoted to peer-reviewed senior position, GS-14 Research Chemical Engineer, in 2011. Currently he works as a research chemical engineer in the Office of Pharmaceutical Quality, Office of Process and Facility to conduct New Drug Application (NDA), Abbreviated New Drug Application (ANDA), and Investigational New Drug (IND) reviews. Additionally, Huiquan serves as the chair of OPF's Advanced Manufacturing Community of Interest (AMCOI) and the director of the American Society for Chemical Engineers (AIChE) Pharmaceutical Discovery Development and Manufacturing (PD2M) Forum.

Huiquan established the FDA's manufacturing PAT research infrastructure at the FDA headquarter research laboratory. He has initiated and conducted systematic PAT studies for a variety of different process across both small molecule drugs and biotech products, and has published 39 peer-reviewed papers. He has a frequent invited speaker for both international and national conferences.

He has received many special honors dating back to 2005 from various organizations and FDA. He will be honored with the Professional Achievement Citation in Engineering (PACE) Award at Iowa State University October 27, 2017.

The Graduate Seminar Series events are part of the required curriculum for chemical engineering graduate students, but open to all Iowa State University graduate students, postdoctoral researchers, scientists, faculty and staff. See the full seminar schedule at cbe.iastate.edu/seminar-series/