The Hong Kong University of Science & Technology

Division of Biomedical Engineering
Department of Chemical & Biomolecular Engineering

JOINT SEMINAR

Date: 9 May 2014 (Fri)
Time: 11:00am
Venue: LTK

Topic: Advancing Regulatory Science in Engineering Education – Product Quality and Process Safety

Speaker: Prof. Henry Y. Wang
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The University of Michigan

Abstract

Given that biomedical, pharmaceutical and related life sciences industries rely heavily on laws and regulations to ensure product quality and patient safety, engineering students should have a basic understanding about the role of their functions and their impact on food, drug and other medical product innovation, design, development and manufacturing processes. The global community increasingly recognizes the need to base these legal and regulatory decisions on state-of-the-art scientific knowledge and engineering practices, and also to understand the various socio-economic incentives and influences beyond traditional regulatory approval/oversight of these products. This lecture shall primarily focus on the scientific and technical rationale behind various regulatory science issues beyond introducing regulatory product approval pathways. Several key regulatory science concepts such as Target Product Profile (TPP), Benefit-Risk Assessment, Quality By Design (QbD) and the critical need of a globally harmonized quality system for various life science products shall be discussed.
**Biosketch**

Dr. Wang has over 30 years of academic and industrial experience in pharmaceutical and biopharmaceutical research, development and engineering. He has over 130 publications and extensive industrial consulting experience. He was instrumental in starting up the interdisciplinary graduate degree program in Pharmaceutical Engineering at The University of Michigan (UM) since 2000. The main focus of his research is to design, develop and commercialize new and emerging biologics and biopharmaceuticals like vaccines and therapeutic proteins. Rapid biologic development, cost effective patient screening and made to order therapeutic biomanufacturing are some areas of my current research interests.

**ALL ARE WELCOME**