"Advanced Pharmaceutical Manufacturing using Process Systems Engineering"

Wednesday
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3:00 pm
Wu and Chen Auditorium
Levine Hall

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Abstract

The pharmaceutical industry has been very innovative and successful in the field of new drug formulation discovery and development. However, this has drawn the focus away from the development of efficient manufacturing methods and process understanding. Due to the lack of knowledge of how critical material attributes and process parameters affect end-point attributes, combined with ineffective control strategies, pharmaceutical products are characterized by a large amount of variability that would not be tolerated in other process industries.

Recently, the Food and Drug Administration (FDA) has recognized the deficiencies of pharmaceutical product manufacturing and has launched an initiative for enhancing process understanding through Quality by Design (QbD) and Process Analytical Technology (PAT) tools. The major goals of this effort can be summarized into the development of mechanistic understanding of a wide range of processes; harmonization of processes and equipment; development of technologies to perform online measurements of critical material properties during processing; performance of real-time control and optimization; minimization of the need for empirical experimentation and finally, exploration of process flexibility or design space. As a result of this effort to change the mindset in pharmaceutical manufacturing, transition of the production in batch to continuous mode is becoming more appealing to the industry and regulatory authorities.

However, continuous production requires detailed process understanding in terms of the evolution of all critical material properties as a function of its operating parameters and environmental conditions. Once process knowledge is translated into models, process systems engineering tools allows the design, analysis and optimization of continuous integrated processes. The major challenges to achieve this goal, and highlights of the work that has been performed in our lab in the recent years to address these problems will be covered in the talk.

Bio

Marianthi Ierapetritou is a Professor and Chair in the Department of Chemical and Biochemical Engineering at Rutgers University. Her research focuses on the following areas: 1) process operations; (2) design and synthesis of flexible production systems focusing on pharmaceutical manufacturing; 3) modeling of reactive flow processes; and 4) metabolic engineering with focus on biopharmaceutical production. Among her accomplishments are the 2016 Computing and Systems Technology (CAST) division Award in Computing in Chemical Engineering, the Award of Division of Particulate Preparations and Design (PPD) of The Society of Powder Technology, Japan; the Outstanding Faculty Award at Rutgers; the Rutgers Board of Trustees Research Award for Scholarly Excellence; and the prestigious NSF CAREER award. Dr. Ierapetritou obtained her BS from The National Technical University in Athens, Greece, her PhD from Imperial College (London, UK) in 1995 and subsequently completed her post-doctoral research at Princeton University (Princeton, NJ) before joining Rutgers University in 1998.

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