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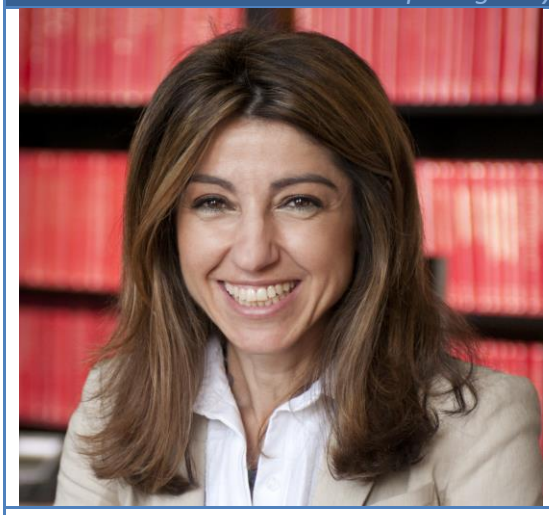

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Modeling for Advanced Pharmaceutical Manufacturing

Abstract:

There are a number of challenges that the industry faces in order to transition towards more competitive, systematic and efficient manufacturing. Regulatory authorities have recognized the deficiencies of pharmaceutical product manufacturing and aim to enhance process understanding through Quality by Design (QbD) and Process Analytical Technology (PAT) tools. As a result of this current effort to change the mindset in order to mimic the rest of the chemical industry, an additional transition is becoming more and more appealing: transition from batch to continuous production mode. However, continuous manufacturing 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, computer aided dynamic simulation tools will allow the design, analysis and optimization of continuous integrated processes.

In this talk I will discuss the work that has been done in my lab towards the development of an integrated platform that will enable the efficient flowsheet simulation and analysis, the assessment of design alternatives, the feasibility analysis of the production line, and the control and optimization of process design and operations.

The developed flowsheet model includes modules for all the necessary unit operations, namely powder feeding, mixing, roller compaction, tablet press and milling integrated to represent a tablet manufacturing line. Models used to represent each unit operation vary from empirical, first-principle or hybrid. Population balance models are developed in order to track the composition and particle size changes throughout complex powder processes dynamically. The developed flowsheet simulation is used to predict the propagation of upstream disturbances to final product quality, the assessment of recycle stream benefits, the identification of process integration bottlenecks and evaluation of different control strategies in order to retain the process within its design space. In addition, global dynamic sensitivity analysis is performed to identify critical process parameters not only within each unit operation, but also between different processes. Finally, simulation based optimization techniques enable the identification of the optimal operating conditions, as well as the optimal design sequence which leads to pharmaceutical tablets with desired characteristics. This work aims to merge knowledge, experience, experimental results and modeling tools for developing a dynamic simulation platform that will enable the safe implementation of the transition towards continuous pharmaceutical manufacturing.

Biography:

Marianthi Ierapetritou is a Professor and Chair in the Department of Chemical and Biochemical Engineering at Rutgers University in Piscataway, New Jersey. Dr. Ierapetritou's 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. Her research is supported by several federal (NIH, NSF, ONR, NASA) and industrial (BMS, J&J, ExxonMobil, Honeywell, Cardinal Health) grants.

Among her accomplishments are the Outstanding Faculty Award, the Rutgers Board of Trustees Research Fellowship for Scholarly Excellence, and the prestigious NSF CAREER award. She has more than 180 publications, and has been an invited speaker to numerous national and international conferences.

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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