Amgen Seminar Series in Chemical Engineering

in

Cherry Auditorium, Kirk Hall, 1 PM

Presents on February 25, 2016

Crystallization Process Design for Pharmaceutical Manufacturing

By

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Crystallization is a key unit operation in the pharmaceutical industry. The control of crystallization processes can be challenging when undesirable phenomena such as particle attrition and breakage occur. This seminar describes the design of highly efficient and controlled processes for the crystallization of pharmaceuticals and amino acids, where crystal properties are especially important for the reliable operation of downstream processes and efficacy of drug products.

Crystallization designs are described in which (1) undesirable phenomena do not occur and (2) the phenomena that do occur are carefully controlled. A crystallizer is described that employs micromixers designed to provide controlled nucleation to generate crystals that are highly uniform in size. The slurry flow is combined with an air flow and fed to a tube to induce a multiphase hydrodynamic instability that spontaneously generates well-mixed slugs where the crystals continue to grow. These slugs are well-mixed without having the mixing blades as in traditional crystallizer designs that induce undesirable particle attrition. Additional degrees of freedom for the control of crystal growth are created by spatially varying the temperature profile along the tube. An alternative design is described that replaces the micromixer with the application of focused ultrasonication. Experimental validation confirms that the proposed crystallizer designs reduce production time and equipment cost by orders of magnitude while suppressing secondary nucleation, attrition, and aggregation—dominant but undesired phenomena that worsen the ability to control the crystal properties.

Biosketch

Mo Jiang is a Ph.D. (2015) and postdoctoral associate in chemical engineering at the Massachusetts Institute of Technology (MIT) with Prof. Richard D. Braatz in the area of process design for pharmaceutical crystallization. His research has been recognized by the AIChE Process Development Division Student Paper Award, the AIChE Separation Division Graduate Student Research Award, the ACS Graduate Student Symposium Award in Industrial & Engineering Chemistry, and the AAPS Graduate Student Symposium Award in Manufacturing Science & Engineering. He received a B.S. in 2006 from Tsinghua University and an M.S. in chemical engineering in 2008 from the University of Illinois at Urbana-Champaign. Before joining the Ph.D. program at MIT, he interned at Boehringer Ingelheim Pharmaceuticals Inc. and Abbott Laboratories (now AbbVie), where he optimized the crystal form of an active pharmaceutical ingredient and designed dual-impinging-jet micromixers to manufacture crystals of desired sizes.

This series at the University of Rhode Island is made possible through the generosity of Amgen, West Greenwich, R.I.

Refreshments provided by the Joseph Estrin Endowment.