Amgen Seminar Series in Chemical Engineering

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Molecular Engineering for Integrated Product Development

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Traditionally the innovation process for new products proceeds linearly through three stages: discovery, development and scale-up to launch. While this can be successful in many cases, failure in the scale-up phase is common and costly, particularly in pharmaceutical product development when an average of $430 million is spent on research per drug prior to human trials. The likelihood of successful transition to scale-up and launch can be increased by employing an integrated approach to innovation, where the effects on molecular level behavior of manufacturing processes and the highly complex mixtures used for scaled-up products are considered throughout the discovery and development phases. As part of a center dedicated to transitioning pharmaceutical manufacturing from batch to continuous processes, I focused on developing a downstream processing technology, electrospinning, to be useful for producing a wide variety of pharmaceutical products, including those containing crystalline and amorphous drug forms. With an integrated innovation approach, molecular level behavior of the drug and polymer characterized by solid state NMR was tied to the end product properties as well as influences from the manufacturing process. This enabled the development of a process to produce electrospun products containing crystalline drugs as well as provided confidence for producing stable amorphous drug forms. Based on this detailed understanding of the product and process, electrospinning was selected as one of the technologies to incorporate into the start-up that formed from the center, Continuus Pharmaceuticals.

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