

133e Expedite Development and Commercialization of Pharmaceuticals with Process Modeling and Scheduling Tools

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The successful development, scale-up, and commercialization of active pharmaceutical ingredients (APIs) and final pharmaceutical products is a challenging task that requires collaboration of professionals from many disciplines. Process simulation and scheduling tools can facilitate this task by introducing a common language of communication among the various teams involved in process development and product commercialization. They can facilitate answers to the following questions: What is the impact of alternative synthesis routes on the economics and environmental impact of a process? What are the cost sensitive steps of a process that need further development and optimization? What process changes can reduce cycles times and lower manufacturing cost? What changes are required in an existing multi-purpose facility to accommodate the manufacturing of a new product? Our experience in addressing the above and other pertinent questions will be presented using examples from the pharmaceutical and biopharmaceutical industries. The examples will cover production of bulk intermediates as well as manufacturing of final pharmaceutical products.