

## **76b The Role of Simulation and Scheduling Tools in the Development and Manufacturing of Pharmaceutical Products**

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The successful development, scale-up, and manufacturing of pharmaceutical products in tablet, capsule, vial and other formats 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 manufacturing. They can facilitate answers to the following questions: How many mixing vessels and other equipment items and of what size are required to make a batch of a certain size? What step in the process has the longest cycle time that determines the process cycle time and the throughput of the entire production line? What process changes can reduce cycles times and lower manufacturing cost? How many cleaning-in-place (CIP) skids are required to clean the equipment efficiently without becoming the bottleneck? What changes and new equipment are required in an existing multi-purpose facility to accommodate the manufacturing of a new product? What is the production capacity of an existing facility for a certain range of products? What is the impact of campaign size on manufacturing and inventory costs? 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 tablets, capsules, soft gels, and vials.