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## **The three gears of success: a framework to tackle a need for expanding production capacity**

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With diabetes being one of the world's fastest growing health emergencies, demand for diabetes medication is rising. This calls for expanding production capacity through construction of new facilities as well as increasing capacity within existing facilities. In this work, a systematic method for capacity ramp-up based on data-driven modelling and simulation of an API purification process is presented. The framework of the method can be described as synergy of three domains (gears): operation, process, and equipment, where accounting of those leads to success in the capacity expansion.

The work started by systematically developing the virtual representation of a physical manufacturing system (i.e. digital twin) for current state quantification and highlighting of a limiting step on a production line. Considering a new process description, the model was then applied to explore potential areas for further improvements in all three domains. The model-based analysis led us both to identify the need for process control modeling, and to define and execute targeted experiments in the lab scale for further modification of the process description and process topology. Finally, to achieve future demand, the roadmap of changes on a production line was proposed and then was split into project packages based on resource availability and complexity of the changes.

In summary, the focus of this work was to demonstrate the importance of systematic approach for continuous evaluation of the design and operational space through simulation, subject to the available knowledge. In addition, the digital twin has supported decision making for investment project by visualization of effects of proposed changes, and to define required experiments and tests in production. Supporting decision making, series of changes in all three domains were proposed to build a roadmap of projects which take the process from the current to the desired future states.

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