The pharmaceutical industry has been very innovative and successful in the field of new drug formulation discovery and development. However, this has drawn the focus away from the development of efficient manufacturing methods and process understanding.

Recently, the Food and Drug Administration (FDA) has recognized the deficiencies of pharmaceutical product manufacturing and has launched an initiative for enhancing process understanding through Quality by Design (QbD). The major goals of this effort can be summarized into the development of mechanistic understanding of a wide range of processes; harmonization of processes and equipment; development of technologies to perform online measurements of critical material properties during processing; performance of real-time control and optimization; minimization of the need for empirical experimentation and finally, exploration of process design space. As a result of this effort to change the mindset in pharmaceutical manufacturing, transition of the production from batch to continuous mode is becoming more appealing to the industry.

However, continuous production requires detailed process understanding in terms of the evolution of all critical material properties as a function of its operating parameters and environmental conditions. Once process knowledge is translated into models, process systems engineering tools allows the design, analysis and optimization of continuous integrated processes. The major challenges to achieve this goal, and highlights of the work that has been performed in our lab in the recent years to address these problems will be covered in the talk.

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