Leveraging Fit for Purpose Drug Release Models to Help with Formulation Development and Scale-up Efforts

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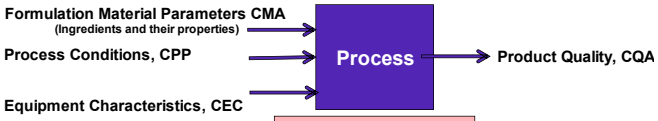
The quality of a product produced from a process is dependent on how it is formulated (the ingredients, their composition), but also on the process conditions of production, and the characteristics of the equipment used. Understanding of the interaction of these different factors, in addition to how the ingredients of the formulation interact with each other is important to achieve a consistent product quality. This is especially true for pharma and specialty materials industry, where consistently maintaining finished product quality is critical. Hence formulators need to account for these interactions early on in their formulation development efforts and ensure they go hand in hand with the process/scale-up ones. A combination of fit for purpose process and application specific models can be leveraged to get actionable insights into the necessary experimentation to meet drug product quality attributes.

This poster focuses on an example case study in this direction from the pharma space of sustained release microspheres products. It shows how a model for drug release [1] can be leveraged to bring insights into necessary experimentation to troubleshoot issues with variability in finished product's drug release rates. Use of such customized application specific models along with process models can help provide predictability to (and address troubleshoot such issues during) scale-up.

Such customized tools facilitate the scientists and engineers in the industry to effectively leverage the power of simulations in their routine needs.

1. *Mehan, et al AIChE Annual Conference, 2016*

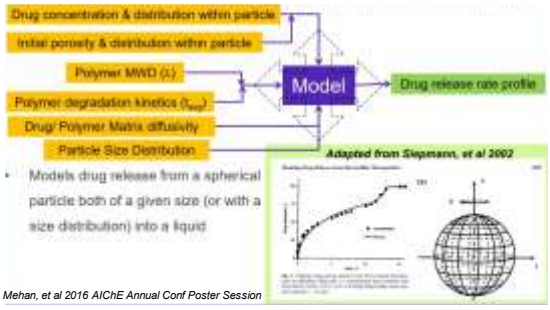
Factors Influencing Product Quality



- Formulation aspects ***not alone, but in conjunction*** with process conditions and the equipment characteristics impact the quality of the product produced
- Hence its important to consider relevant interactions of the formulation with process/ equipment in
  - Any formulation development exercise, and
  - Use of any experimental or modeling/ simulation strategies

Drug Release Application Model

- A fit for purpose model to help understand impact of various parameters



Mehan, et al 2016 AIChE Annual Conf Poster Session

Significance

- Modeling approaches enable identify the right areas and experimental methods to focus on to address IVR issues
  - Drug/ polymer interactions (i.e., drug diffusivity) more important
    - ➔More focus on factors like:
      polymer MW
      the ratio of solvent to polymer.

Sample	Release Rates
A	5X
B	10X
C	X
D	15X

- In combination with process modeling efforts for scale -up, such fit for purpose models on IVR
  - facilitated decision making on the critical experimentation during formulation development and
  - troubleshoot scale-up concerns