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Regulatory impact of applying computational predictive models to design, develop, and commercialize drug products

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Abstract

The budget-restricted pharmaceutical environment is countered by the heightened expectations for drug products to be developed using science-based principles. These two opposing factors have created a crucial opportunity for engineering principles to be applied and implemented across the industry. In this presentation, drug product modeling techniques applied to formulation and processing operations are discussed as support to the design, development, and scale-up for solid oral drug products. These process modeling techniques are discussed and exemplified with case studies ranging from raw material specifications and formulation property predictions to process parameter predictions. The major processing to produce tablets include i) powder processing; ii) dry and wet granulation; iii) tablet compression; and iv) film coating. Specific consideration has been given to the impact of these models on the regulatory submission and review process.

Biography

Mary am Ende is a Research Fellow in Drug Product Design at Pfizer in Groton, Connecticut. She received her B.S. in chemical engineering from the University of Iowa in 1988 and her Ph.D. in chemical engineering from Purdue University in 1993. Mary's research interests have been in the formulation development of solid oral dosage forms, with focus on osmotic drug delivery systems. More recently, her interests are in the field of process development and use of predictive tools to streamline commercial development and scale-up through process modeling. She has published over 15 papers, 5 patents, and 50 presentations. Her current responsibilities include the development and use of process models and engineering technologies to support dosage form development and commercialization. Mary is a member of the American Institute of Chemical Engineers (AIChE) and the American Association of Pharmaceutical Scientists.