Abstract:

“Pre-formulation and Early Formulation Development: Assessing Risks and Strategies”

Preformulation and exploratory formulation development studies are critical in defining drug product strategies for first in human studies leading to commercial dosage form development. Exploratory development is a dynamic phase of development with limited API, tight timelines, limited knowledge of material properties and process scale up and the impact of dose change, formulation and physiological variables on bioavailability being unknown. Using an integrated approach to assess risks related to biopharmaceutics, material (form) and drug product processing is critical to design appropriate formulation strategies.

Use of in vitro tools, in silico absorption modeling along with in vivo studies and high throughput screening techniques not only provide a robust design space early on but also lead to focused formulation development with shorter timelines.

Through various case studies, this talk will cover tools and workflows that can be implemented in the preformulation and early formulation development space to assess biopharmaceutics, API form and phase transformations and drug product processing risks, highlighting a qbD approach to early development.