

Variability in Oral Exposure – Formulation Investigations and Mitigating Approaches

Systemic exposure following oral administration of drugs is dependent on multiple parameters and inter- or intra-subjects variability in exposure can impact the efficacy and toxicity of compounds. When variable exposure is observed at the preclinical stage, the causes can be investigated. These can be related to physicochemical properties of the compounds, impacting solubility, dissolution, precipitation or permeability. They can also be associated with physiological states or interactions with enzymes and/or drug transporters. Hypotheses can then be proposed and mitigating approaches can be tested.

The presentation will review the various factors impacting oral absorption and exposure. Case studies describing the strategy and steps followed to identify the most relevant approach to address the variability observed will be presented.