

“Pre-formulation Strategies and Non-Clinical Inputs: Derisking Clinical Topical Formulation Selection”

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Abstract: This presentation will discuss a systematic approach to developing a topical formulation and strategies used to mitigate risks during formulation development. These strategies include pre-formulation considerations, including drug substance physicochemical characterization, solubility, excipient compatibility, and stability assessments, which are important studies for developing a drug substance centric formulation. Also, will briefly discuss considerations for building confidence in a non-clinical study approach to aid in formulation selection.