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From preclinical to IND formulation development: Using a QbD risk based approach

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Statement of the Problem: Preclinical formulations development leading to IND enabling studies present a unique platform opportunity whether it is in support for ADME & toxicity studies, preliminary safety / efficacy assessment, patent exclusivity, or life-cycle-management product endeavors. The work presented here describes a systematic pathway using a risk management based approach during formulation platform screening. This includes the use of simples solvent to cosolvent, nano suspension and spray-dried amorphous solid dispersions intended for parenteral, oral systems, among others. FMEA and Quality-by-Design elements are implemented with the aim of providing high drug load and stable formulations in efforts to achieve a desired *in-vivo* exposure. Case studies using a low solubility/low permeability drug candidate is presented using various cosolvent systems as well as HPMC/HPMC-AS and surfactants for spray-dried amorphous solid platforms. Structure-based relationships with solubilization characterisitics are also presented. Results from the case study demonstrate high solubilization using pyrrolidone based solvents suggesting a strong structure-solubility relationship at the N--H and C=O bond level producing over 100x solubility increase when compared to water and significant *in vivo* exposure. The outcome of this work is supported by comparing *in-vivo* animal plasma data for further bridging studies and IND enabling studies during product development.

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