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Formulation selection matrix in early clinical formulation

The pharmaceutical formulation development of early stage pre-clinical and clinical formulations poses various unique challenges during development. These challenges are mainly related to limited physicochemical data, limited availability of drug substances, uncertainty on dosage ranges, solubilization, *in vivo* exposure challenges, further scalability considerations for clinical manufacturing etc. The presentation covers an opportunity area for formulation selection matrix based on Data Driven Decision (DDD) making during develop ability assessment and solution engine that can facilitates overall development approach. Over 60% of New Chemical Entities (NCE's) under development are poorly soluble therefore, it is always challenging to select appropriate development platform. The presentation covers and describes technology selection such as micro-evaporation, amorphous solid dispersions using spray drying or hot melt extrusion (HME) and few case studies describing the same. Overall, appropriate assessment of early stage data can help to successfully develop formulations within defined timeframe with limited usage of drug substances. These formulations can be further evaluated in animal models or first in human (FIH) clinical studies to understand *in vivo* performance followed by phase appropriate scale up.

Biography

Anand Kulkarni has over 14 years of research experience in the Pharmaceutical Industry including generics, OTC and New Chemical Entities (NCE) development, scale up, technology transfer, registration, where he was involved in the overall end to end project management. Prior to joining BioDuro, he was associated with Yangtze River Pharma group (in-source collaboration center), WuXi AppTec, US Vitamins and Wockhardt Ltd in multiple roles and responsibility. In these roles, he was involved in supporting various phases of generic and new drug development projects including conventional platform as well as HME, spray drying, nano-sizing and other challenging technology platforms. He has over eight patents/applications and various publications to his credit and participated in various national and international conferences. He is a recipient of several prestigious awards and fellowships during his academic and professional career.

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