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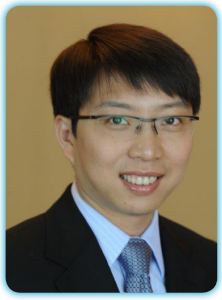

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Effective utilization of preformulation studies to guide drug product development

Preformulation study is starting point of new drug development program and defines the strategies for drug product development. It is critically important to utilize various preformulation characterization techniques to fully profile the preclinical candidates from various aspects to avoid any surprise in late stage of product development. The major preformulation aspects include molecular properties (solubility, stability, UV absorptivity, partition coefficient, etc.), solid-state properties (crystal form, thermal properties, particle size, etc.), API form development (salt screening, polymorph screening, particle size control, etc.), and formulation development support (toxicity formulation, enabling formulation development). Normally at early stage only very limited amount of API is available to be used in preformulation studies, thus a very full check list of all preformulation studies is not feasible for most drug development program. These studies need to be tailored based on the target product profile and unique properties of the drug candidate so that the appropriate development strategies can be well defined to mitigate any potential risk during the whole drug development process. Typical pitfalls and risk scenarios in new drug development will be discussed and explained to show how to effectively utilize preformulation studies to guide drug product development.

Biography

Tao Feng is currently a Senior Director of CMC at ZaiLab, responsible for drug product development and manufacturing to support ZaiLab's clinical and commercial programs. He has more than 12 years' experience in new drug research and development including preclinical candidate characterization, preformulation, formulation development and GMP manufacturing. Prior to joining ZaiLab, he was the Director of Pharmaceutical Development at WuXi Apptec, responsible for formulation development and GMP manufacturing of many new drug programs. Prior to WuXi Apptec, he has worked at Schering-Plough in New Jersey US, where he led the preclinical candidate characterization activities to support multiple new drug discovery programs to progress into development phase. He has received his PhD from Purdue University, USA.

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