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Drug delivery and solid state chemistry at the drug discovery-development interface

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Over the past decade, scientific and business needs have pushed pharma to more closely align drug discovery and drug development efforts in order to bring optimal Pre-Clinical Drug Candidates (PCCs) forward. Towards this end, pharma development chemists at Merck now routinely provide innovative rationally designed drug formulations ranging from nanoparticles to amorphous dispersions for key pre-clinical animal studies. They also work closely with medicinal chemists to optimize PCCs' physicochemical properties and identify a crystalline phase that has appropriate characteristics that will allow for good performance in pre-clinical safety studies and clinical formulations. In all cases, miniaturization and state-of-the-art characterization methods are essential. Early investment in these areas can significantly shorten the time to the clinic and help avoid ugly surprises related to API phase and exposure. One of the most exciting aspects of working in this space is the many opportunities for innovative collaboration between biologists, chemists, pharmacologists, etc., investigating new drug delivery modalities and administration routes in a wide range of preclinical species. This presentation describes the unique tools a Merck uses in discovery space and shows some examples where partner groups from discovery and development worked together to increase the speed of drug lead identification, biopharmaceutical optimization and the PCC clinical approval process.

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Quality by design and particle engineering via spray drying

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Efforts to understand and control particle formation processes have been intensified in the last decade, coinciding with the development of pulmonary therapeutics that were traditionally given by injection triggering the development of diverse administration systems and particle engineering strategies. To date, the process that drives particle formation is not fully understood yet due to the interaction among many parameters. Therefore, the prediction of the final size, morphology and solid state is complicate requiring a deeper understanding. For this reason, the main aim of this project is to investigate which parameters play a key role in the particle formation process and how these properties (parameters) can be model in order to predict the final optimal particles with the desired characteristics. The potential use of this basic research could be applied to multiple disciplines, we are focus on getting the right particle to pulmonary drug delivery. The key of successful particle engineering is controlling the mechanisms that determine the solid state as well as the radial distribution of components during the drying process when more than two components are spray dried together. Several driving forces that may be responsible for separation of components have been suggested. Surface activity may lead to preferential adsorption of components on the droplet surface, causing a diffusional flux toward the surface.

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