



Prof. Karl Wagner

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Title: Solid State Modification, Characterization and its Applicability for Life Cycle Management of a Drug Product.

Abstract : Despite the availability of various enabling technologies, a lot of marketed BCS class II and IV drugs suffer from an appropriate utilization of them. Subsequently, the achieved bioavailability gives room for optimization, which in turn could lead into a new drug application according to the FDA's 505 (B)(2) regulation. In this regards the talk will focus on how manipulation of the solid state of the API or the formulation affects solubility, release kinetics and potentially bioavailability, whether this is amorphization, improved wetting, solubilization, maintaining supersaturation, etc.. Next to formulation strategies, the talk will highlight an in vitro screening tool to discriminate the impact of the various enabling tools. Using our miniaturized bi-phasic dissolution model enabled us to discriminate between various formulation principles proven by several level A IVIVCs. Lastly, the talk will highlight the potential of melt extrusion to optimize hydrophobic matrix tablets and how to utilize this for floating drug delivery devices potentially used as gastro retentive systems.

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Professional Biography

Dr. Karl Wagner is a Professor for Pharmaceutical Technology and Bio-pharmacy at University of Bonn, Germany. Prior to this, he was Head of Laboratory for new technologies and external co-operation at Boehringer Ingelheim, Germany. He has obtained his post doctorate from College of Pharmacy, University of Texas, Austin. He has done extensive research in controlling drug release using ion-exchange resins and ion controlled drug release of multiparticulate drug delivery systems. Dr Karl's research work also encompasses PBPK modelling, solubility enhancement, site specific drug release, hot melt extrusion and continuous manufacturing.