

4th International Conference and Exhibition on Pharmaceutics & Novel Drug Delivery Systems

March 24-26, 2014 Hilton San Antonio Airport, San Antonio, USA



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Enabling the development and life cycle management of oral poorly soluble drugs using lipid-based drug delivery systems

Lipid-based systems are widely used in drug development and life cycle management to enhance the solubility and oral bioavailability of poorly soluble drugs (BCS II and IV) with several drug products on the market. Despite the progress, however, a pharmaceutical formulator is often contemplating with a number of questions: a) why to consider lipid-based systems over other approaches? b) When lipid excipients and formulations can be applied based on the physicochemical properties of the drug substance? and c) What specific lipid formulations and dosage forms to use for expeditious proof of concept studies? This presentation will address these questions and guide the pharmaceutical formulator through preformulation, feasibility studies and formulation development work. Characteristics of lipid excipients and formulations along with a biopharmaceutical rationale for their use with poorly soluble drugs will be discussed during the first part of the talk. Specific dosage forms, such as, liquid filled hard and soft gelatin capsules, as well as solid dosage forms (tablets and capsules) incorporating lipids will be addressed during the second part of the presentation and compared against certain desired product development characteristics. Then, case studies with BCS II and IV drugs, marketed and NMEs, will highlight biopharmaceutical benefits using lipid formulations which include, improved pharmacokinetics, promotion of lymphatic absorption and inhibition of intestinal metabolism and efflux pumps. The talk will conclude with lessons learned to date and future perspectives in the field.

Biography

Panayiotis P Constantinides is the President of Biopharmaceutical & Drug Delivery Consulting, LLC with 25 years of experience in drug delivery and pharmaceutical development. He received a University Diploma in Chemistry from Athens University in 1977 and Ph.D. in Biochemistry from Brown University in 1983. He was a postdoctoral fellow in the Pharmacology Department and Associate Research Scientist in the Comprehensive Cancer Center of Yale University School of Medicine (1983-1987). Past industrial positions held includes: Vice President of R&D with DOR Biopharma and Morton Grove Pharmaceuticals (2001-2004), Director of Research at SONUS Pharmaceuticals (1997-2000) and from 1987 to 1997 a number of R&D positions of increasing responsibilities with LipoGen, SmithKline Beecham Pharmaceuticals and Abbott Laboratories. In addition, he serves as scientific advisor in early stage companies and contract research organizations. He is inventor in 33 patents and patent applications and has authored more than 130 publications and presentations at many national and international conferences and universities. He is AAPS Fellow, current Vice Chair of the AAPS Formulation Design and Development (FDD) Section and Past Chair of the Lipid-Based Drug Delivery Systems and the Nanotechnology Focus Groups.

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