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Nanomedicine by different routes of delivery

here are many significant hurdles for a pharma or biotech company to overcome during the development process. The high failure rate in drug development shows that only 1 in 5,000 discovery compounds will reach the market, and one in every five drug candidates will gain approval. A dramatic increase in the percentage of the new chemical entities (NCEs) with poor physical, chemical, and biopharmaceutical properties (BCS II and IV) 4 in the drug pipeline has played a significant role in attributing to those high failure rates and increase in development timelines. About 50% of drugs on the market and nearly 90% of molecules in the

discovery pipeline are poorly water-soluble. Administration of those compounds by parenteral route without causing injection site reaction and systemic toxicity effects constitutes another barrier. Numerous drugs associated with poor solubility and low bioavailability have been successfully formulated into drug products for clinical studies by a suite of available formulation technologies. Many marketed drugs have been successfully reformulated to improve efficacy, safety and patient compliance using the NDA 505(b)(2) regulatory pathway. Revitalization of older marketed drug products using innovative drug delivery technologies or platforms can provide new marketing exclusivity and new patent protection, and thus offer an effective tool for product life cycle management.



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Biography

Jim Huang founded Ascendia after years of pharmaceutical R&D experience at Pfizer (ex-Wyeth), Baxter, AstraZeneca, and Roche. He has led the formulation development efforts for the successful transition of several oral and parenteral dosage forms from discovery through formulation, manufacturing, technical transfer and ultimately commercialization. He holds a Ph.D. in Pharmaceutics from the University of the Sciences in Philadelphia (formerly Philadelphia College of Pharmacy and Sciences) where he worked with Professor Joseph B. Schwartz.

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