

9th World Drug Delivery Summit

June 30-July 02, 2016 New Orleans, USA

Trials and tribulations of novel drug delivery systems

Rajiv Nayar

HTD Biosystems, USA

Demand for drug delivery product in the US will rise 6.1% yearly to \$251 billion in 2019. Parenteral products will grow the fastest, driven by monoclonal antibodies and polymer/liposomal encapsulated medicines. Not only are the drugs becoming more complex (e.g. DNA, siRNA, mRNA, cell-based, modified biologicals, etc) but the DDS employ novel materials and configurations (smart polymers, tunable liposomes, mesoporous silica, graphene nanotubes and biosensors, etc). A significant challenge for both drug and drug delivery systems is to produce existing and emerging drug technologies in a manner that improves drug administration for the patients. Advantages of complex drug delivery systems over traditional systems are more convenient routes of administration, rate or efficacy and duration of drug activity, decreased dosing frequency, improved targeting, as well as reductions in toxic metabolites. An equally important consideration is the concept of making the drug delivery system a pharmaceutically acceptable drug product. The challenges involved in making a Drug Product Delivery System (DPDS) are issues that include safety, stability and manufacturability, cost of goods and being reimbursable. These issues that need to be addressed in CMC of the DPDS will be discussed as they are a critical component in bringing a novel DDS containing a biopharmaceutical to market. Some recent case histories will be discussed as examples.

Biography

Rajiv Nayar is the Founder and President of HTD Biosystems. Previously, he was at Bayer where he established the Formulation and Drug Delivery Group in the Biotechnology Division and was responsible for managing the formulation and drug delivery activities within the global Bayer network on protein/peptide based drugs. He was a recipient of 3 consecutive Presidential Achievement Awards at Bayer for implementing Continuous improvement processes in pharmaceutical development. He is an inventor on 15 patents and has authored over 70 publications. He is the Inventor of the Bayer's albumin-free Factor VIII formulation (Kogenate® FS). Prior joining Bayer, he was at the Canadian Liposome Company and involved in the development of liposomal doxorubicin (Caelyx®, Myocet®). He has received his PhD (Biochemistry) from University of British Columbia and was a MRC fellow at MD Anderson Tumor Institute.

nayarr@gmail.com

Notes: