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World Drug Delivery Summit

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High throughput formulation strategies for biotherapeutics

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The objective of High Throughput Formulation is to speed up formulation development by rapidly progressing the purified biotherapeutic protein/peptide into a drug product that can be evaluated in clinical studies. There is an impending crisis in the pharmaceutical industry. Over the past 20 years, heavy investment into drug discovery research, genomics, proteomics, systems biology, and high throughput screening has resulted in an overwhelming number of potential drug candidates. Now research is no longer the bottle neck, development is. We are now faced with the challenge to develop more drug candidates with less material, in shorter time frames, with better stability and appropriate drug delivery systems/devices. Efficient formulation strategies will be discussed that involve implementation of nanotechnologies to perform complex analytics, use of advanced algorithms and experimental designs that minimize number of experiments and maximize the information from the data. New approaches for formulating biotherapeutics will be discussed that utilize thermodynamic parameters rather than traditional analytical approaches to identify stable formulations prior to performing time-consuming and expensive stability analysis on many candidate formulations. Examples of such approaches to formulation development will be presented.

Biography

Rajiv Nayar is 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 to Bayer, he was at the Canadian Liposome Company and involved in the development of liposomal doxorubicin (Caelyx®, Myocet®). He received his PhD (Biochemistry) from University of British Columbia and was a MRC fellow at M.D Anderson Tumor Institute.

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