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Liposome characterization required for regulatory approvals

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Abstract

Liposomes have been considered an outdated drug delivery technology, however this unique nanotechnology system is experiencing a resurgence; especially in oncology chemotherapies. Azaya Therapeutics has developed a patented nanotechnology platform called "Protein Stabilized Liposome" (PSL) and has completed a Phase I trial with its first chemotherapy product - liposomal docetaxel, ATI-1123. Since there are relatively few liposomal products in the US and EU market, regulatory bodies are very conservative and cautious in their assessments. In particular, there is significant scrutiny within the chemistry, manufacturing, and control (CMC) requirements for liposomal products. In fact, both the European Medicines Agency (EMA) and the US FDA view this liposomal nanotechnology within the same paradigm as "biosimilars" with respect to regulatory requirements and characterization. Azaya has developed a battery of tests to support the regulatory approval pathway including a novel in vitro release method applicable to liposomal nanoparticles. This validated method has been rigorously tested to prove that minute changes in the process and raw materials affect the release characteristics of the finished product. Along with the standard physicochemical testing, these in vitro release data could provide robust support in the quality of the product and definitive enough to support a technology transfer and scale up to other manufacturing sites and potentially obviate the need for additional human clinical trials to prove bioequivalence.

Biography

Don Kruppa is currently the Vice President of Operations at Azaya Therapeutics, Inc. in San Antonio, TX and has been with the company since early in 2012. He oversees various functional departments including Regulatory Affairs, Manufacturing, R&D, and Quality Control. He joined Azaya from ICON Clinical Research where he served as Sr. Director of Portfolio and Program Management. Prior to ICON, he worked for eleven years with ILEX Oncology and Genzyme Corp. serving in various roles within program management supporting the development and launch of new oncology therapeutics. While at ILEX Oncology and Genzyme, he provided leadership for several projects from preclinical thru commercial launch including CAMPATH® (alemtuzumab) used for adult leukemia patients and CLOLAR®. (clofarabine) used for pediatric leukemia patients. Later, Mr. Kruppa was involved in the development of LEMTRADA® (alemtuzumab) for multiple sclerosis patients.