

Presentation Summary

Information will be presented to understand the similarities and differences between the EMEA and FDA requirements for initial submission of new medicinal products. Useful practical suggestions and recommendations will be offered to assist with preparation of EU IMPD CTA and US IND submissions. This will include a discussion of typical CMC clinical hold issues and risk factors that should be considered during early drug development as well as a discussion of the FDA guidance describing cGMP Requirements for Phase 1 Investigational Drugs (July 2008).

About the Speaker

Mr. Lane has more than 29 years experience in the pharmaceutical and medical device/diagnostics areas. He currently serves as senior advisor for the pharmaceutical development function at Cato Research and Assistant Managing Director for the San Diego office. Before coming to Cato Research, he served for 8 years as senior director of Manufacturing and Pharmaceutical Development for Maxim Pharmaceuticals and prior to that worked for Accumetrics, Pacific Pharmaceuticals and Lilly subsidiaries, Pacific Biotech and Hybritech. Mr. Lane has had responsibility for directing the pharmaceutical development activities for numerous products, including recombinant and natural proteins, peptides, DNA, stem cells, small molecules, oligonucleotides, radiopharmaceuticals, and devices in parenteral, oral, and topical dosage forms; CMC sections for regulatory filings; defining and designing development plans for sponsors; helping sponsors complete all necessary activities to file successful regulatory documents and helping sponsors manufacture clinical trial material. Other areas of experience include planning and attending a variety of FDA meetings; conducting GMP and GLP audits; and overseeing the complete development programs of various products.

Mr. Lane completed his undergraduate studies in biology/biochemistry at the University of California, San Diego and he received an M.B.A. from the University of Phoenix. He also has certifications in Regulatory Affairs, Production and Inventory Control, and Materials Management.