Tsung-Hung (Max) Li 李宗衡, PhD

Insmed
Director, Regulatory Affairs - CMC

Dr. Li has more than 16 years of experience on CMC regulatory affairs to provide sound scientific reviews to evaluate critical CMC documents for global submissions. He has provided regulatory submission strategy for new drug product registration and post-approval changes. Dr. Li also has in-depth knowledge and extensive experience in interpretation and application of CMC-related ICH, FDA, EU, Japan, and China regulations in successfully global filing and approval of multiple marketing applications. Before transition to Insmed Inc. Dr. Li worked for Merck as Lead CMC Regulatory Affairs for the global submissions and approvals of Asmanex® Twisthaler®, Dulera®, Asmanex® HFA, Zepatier® (US and Japan), Delstrigo™ and Pifeltro™ drug products.