



Biography of Andrew Chang

Andrew has more than twenty-five years' experience in the development, regulation and quality of biologics, pharmaceuticals and combination products. He is responsible for external affairs, providing strategic advice and solutions for quality and regulatory related issues, and expert support to inspection preparation. Since 2013, Andrew has represented Novo Nordisk at several work groups e.g PhRMA, BIO and EFPIA to advocate patient and industry's interests, developing position papers and in liaison meetings with regulatory authorities. As a member of PhRMA and BIO's International Regulatory Policy Work Groups, he represented PhRMA as an expert and topic leader to ICH Q12 Expert Work Group and implementation work group, respectively for developing and implanting guidelines on Pharmaceutical Products Lifecycle Management.

Prior to Novo Nordisk, Andrew served more than eleven years at US FDA, most recently as an Associate Director for Policy and Regulation, Acting Deputy Director, Lab Chief and Senior Regulatory Scientist in the Division of Hematology, Center for Biologics Evaluation and Research (CBER). A leading FDA and CBER spokesperson, he was FDA deputy topic leader, developing ICH Q5E guidelines and the FDA observer for European and US Pharmacopeia's Expert Groups on Blood and Blood Derived Products. During his tenure in the FDA, Andrew received numerous awards for his exceptional and outstanding performance on regulatory review and management, GMP inspection, and policy.