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Dr. Andrew Chang is a multifaceted quality and CMC leader with 25 years well-rounded medical product regulatory and industry experiences. He is a member board director for CASSS-Sharing Science Solutions and the chair for PDA Biopharmaceutical Advisory Board (BioAB). At his current capacity as a Vice President, Quality and Regulatory Compliance, Novo Nordisk Quality, Novo Nordisk, Inc. he is responsible for external affairs, providing strategic advice and solutions for quality and regulatory related issues, and expert support to inspections. Since 2013, Andrew has represented Novo Nordisk at several work groups in industry trade organizations, e.g., PhRMA and BIO to advocate patient and industry's interests by developing position papers and participating liaison meetings with the regulatory authorities. He is the co-chair for BIO Cell and Gene Therapy Task Force, a member of PhRMA and BIO's International Regulatory Policy Work Groups and representing PhRMA as an expert and topic leader to ICH Q12 Expert Work Group and implementation work group, respectively for developing and implanting guideline on Pharmaceutical Products Lifecycle Management. Prior to industry, Andrew had served more than 11 years in 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). While at FDA, Andrew was known as a leading FDA and CBER spokesperson and has presented the FDA perspective at many national and international meetings. He also served as the FDA deputy topic leader for developing ICH Q5E guideline 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 numerus high level FDA awards for his exceptional and outstanding performance on regulatory review and management, GMP inspection, and policy.