International Alliance for
Biological Standardization

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Dr. Andrew Chang is a multifaceted quality and CMC leader with 29 years well-rounded medical product regulatory and industry experiences. He is a board director for CASSS-Sharing Science Solutions and PDA, respectively. Biopharmaceutical Advisory Board (BioAB). At his current capacity as a Vice President, Quality and Regulatory Compliance, Regulatory Policy and Intelligence, Global Regulatory Affairs, Novo Nordisk, he provides strategic leadership on Regulatory and Quality related Policy, External Affairs, strategic advice and solutions to quality and regulatory related challenges.

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 topic lead from BIO for ICH Q6(R1) EWG on Specifications.

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, CBER. He was responsible for management of marketing

application review and inspections and had led CBER effort to develop international standards. Andrew received numerus high level FDA awards for his exceptional and outstanding performance on regulatory review and management, GMP inspection, and policy.

Andrew's formal scientific training includes post-doctor in immunology from the National Institutes of Health, Ph.D. in Biochemistry from the State University of New York, and B.S. in Pharmaceutical Chemistry from the China Pharmaceutical University. He has published numerus peer reviewed scientific papers in JAMA, J.Exp.Med., Blood, J.Immunol., Dev. Immunol. Thromb Haemost., Haemophilia, Pharmaceutical Engineering etc., and has been a frequent speaker at national and international conferences.