

Janeen Skutnik-Wilkinson

Ms. Skutnik is the Associate Director for Quality Intelligence at iogen, the current Chair of IPEC Americas. Her former positions include: Vice President at NSF DBA, Director /Team Leader of Quality & Regulatory Policy at Pfizer, responsible for working with various trade associations and also developing Pfizer Positions on Quality and CMC issues. She has over 24 years experience and expertise in compendial activities, quality and regulatory policy, and has held a variety of positions with responsibilities in documentation, change control, analytical method validation and product launch. Ms. Skutnik earned a Bachelors of Science from the University of Connecticut in 1994. She is a member of the ICH IWG for ICH Q3D Elemental Impurities, and was also on the EWG for Q3D. She was the Chair of PhRMA's Compendial Liaison Team (2000-2012); and the PhRMA Topic Leader for the ICH Topic – Q4B Regulatory Acceptance of Pharmacopoeial Interchangeability. She is the IPEC Delegate to the ICH Assembly and ICH Informal Quality Discussion Group