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TITLE: Comparability Assessment for Changes to Manufacturing Processes: Industry Recommendations on Bayesian Practices

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ABSTRACT: In the pharmaceutical industry, maintaining the quality, safety, and efficacy of drug products is paramount, especially when manufacturing processes change. As outlined in ICH Q5E, comparability following manufacturing changes is supported by the evaluation of relevant data to demonstrate that product quality is maintained and there is no adverse impact on safety or efficacy. This talk will present industry recommendations for employing Bayesian statistical methods for comparability assessments within the Chemistry, Manufacturing, and Controls (CMC) domain. While regulatory agencies have increasingly recognized the value of Bayesian approaches, detailed CMC-focused guidance remains limited. A manuscript in submission, authored by the Bayesian CMC Working Group of the ASA Biopharmaceutical Section, seeks to help address this gap. We discuss quality range and equivalence margin approaches and highlight considerations for prior specification with examples. This work aims to serve as a foundational resource for CMC statisticians and scientists and to promote continued dialogue between industry and regulators toward rigorous guidance for Bayesian analysis in comparability testing.

BRIEF SPEAKER BIO: Ji Young Kim, PhD, Director, Head of CMC Statistics, Quantitative Sciences,
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Ji Young received her Ph.D. in Statistics from the University of Illinois at Urbana-Champaign (UIUC) in 2010. She currently leads the CMC Statistics team at Takeda, where she collaborates closely with Pharmaceutical Sciences groups across the development lifecycle of pipeline assets, from post-discovery through drug approval. She also serves as a co-lead of the ASA Biopharmaceutical Section's Nonclinical Biostatistics Bayesian CMC Scientific Working Group.

Prior to joining Takeda, Ji Young spent six years at Merck in the Center for Mathematical Sciences, supporting vaccine programs as a CMC statistician. She previously worked for five years at the Children's Hospital of Philadelphia (CHOP), where she completed postdoctoral training in Biostatistics and later led biostatistical efforts for multiple sleep and nephrology studies at CHOP/UPenn. Earlier in her career, she was a statistics faculty member at Mount Holyoke College.