



International Alliance for
Biological Standardization



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Dr. Maria Cecilia Tami received a M.Sc. in biology and a PhD in the field of molecular virology from the University of Buenos Aires, Argentina. Dr. Tami joined Genentech-Roche in 2020 as the Head of US Technical Regulatory Policy. In this capacity, she leads and executes CMC regulatory policy strategies and advocacy plans and external outreach in technical and regulatory CMC related topics. Before joining Genentech-Roche, she served for over 12 years in the Office of Biotechnology Products (OBP) in CDER, FDA and held positions of increasing responsibility. She performed and oversaw risk-based CMC/product quality assessments at all phases of product development.

Dr. Tami is actively involved in ICH activities. While at FDA, she served as FDA Topic lead for the revision of ICH Q5A "Viral Safety Evaluation of Biotechnology Products". Currently, she is the deputy Topic Lead in the revision of ICH Q6, representing BIO and she is also the Deputy Topic Lead in the ICH Quality Discussion Groups (QDG), representing PhRMA.

Dr. Tami is an active member of the CASSS community, an international non-profit scientific society. She serves as co-chair in several venues and is currently a member of the WCBP Scientific Organizing Committee. She is also a member of the Innovation and Quality (IQ) Consortium

Regulatory Advisory Committee (RAC), the American Society of Gene and Cell Therapy (ASCGT) CMC Committee and co-chair the Regulatory Considerations Committee (RCC) in The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBLE).

