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Biological Standardization

**Globally Harmonized Specifications: Current State and Future Opportunities**  
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Carol Krantz is Executive Director and Head of Regulatory Affairs, CMC at Seagen Inc. She has been with Seagen since March 2017, and in that time has built a dedicated Regulatory CMC group while supporting global expansion of Seagen and approval of PADCEV, TUKYSA and TIVDAK. Previously, Carol was on the Regulatory CMC leadership team at Amgen, overseeing a portfolio of development and commercial stage products including ENBREL, VECTIBIX and IMLYGIC. Prior to that, Carol was at Immunex in Regulatory, Process Development, Project Management and Supply Chain groups. She also has served as an independent Regulatory CMC consultant for BioNow Consulting and was the Regulatory CMC lead at Sierra Oncology. Carol received a B.A. in Biology from the University of Pennsylvania, her Ph.D. in Immunology/Microbiology from the University of Colorado, Health Sciences Center and did her post-doctoral studies at the Fred Hutchinson Cancer Research Center. She is a member of DIA, RAPS, PDA and an Associate Director for CASSS.

