



International Alliance for
Biological Standardization

7th IABS Statistics Workshop

Accelerating Drug Development: How QbD, Regulatory Partnerships, and Pandemic Learning Can Further Expedite Meeting Patient Needs



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Laura has leveraged her scientific and statistical expertise to drive innovation in biotechnology across operations functions for the past 18 years. Throughout her career, Laura has focused on supporting clinical, late-stage, and commercial biologics and small molecule programs, including determining specifications, evaluating comparability, developing analytical & product lifecycle management practices, and setting overall product quality strategy. She is passionate about teaching statistics to the many dedicated scientists that she encounters in the CMC community.

Laura currently leads the CMC statistics function at Rezolute, where she partners with scientists across CMC functions to integrate statistical thinking into everyday decision making so that the company can advance important medicines through clinical trials. Laura recently acted as a Product Quality Leader at Seagen where she combined statistics with quality technical expertise to develop and defend the commercial dossier for TUKYSA®, which is now approved in 36 countries for use in HER2+ breast cancer patients. Laura began her career by applying statistical and stability knowledge in support of multiple late-stage and commercial programs at Amgen.

Laura holds Bachelor's degrees in chemistry and biochemistry from the University of Colorado and a Master's in applied statistics from Colorado State University. She has served on the IABS Statistics Workshop Scientific Organizing Committee since 2018 and on the AAPS CMC Statistics Community Leadership Team since 2016.

