



International Alliance for
Biological Standardization

11th Annual Statistics Workshop: Big Tent Statistics - Conveying the Importance of Statistical Contributions

October 20-23, 2025
Virtual Meeting

Title The Stability Scientist and Statistician – An Essential Partnership that Delivers

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Examples abound demonstrating the criticality of statisticians throughout pharmaceutical development, registration, and product lifecycle. In this session we will look specifically at how the partnership between stability experts and statisticians has continued to grow and change as science and risk-based stability strategy and program design have evolved. Stability, always essential, has moved beyond a simple compliance mindset with a checklist of studies and data to providing product knowledge and evidence to accommodate global needs and accelerated timelines. We will discuss the importance of communication and collaboration between the stability team and statisticians needed to develop a mutual understanding of the challenges and constraints in the generation and evaluation of stability data. We'll show how this understanding can be used to establish standardized approaches that can be routinely applied within the quality system, provide statistical expertise and solutions for non-routine work, and identify and incorporate innovative approaches as new standards. We'll discuss how updates to international stability guidelines provide even more opportunities (and expectations) within the stability landscape requiring access to statistical partners that are a strategic part of the team, and what this means to smaller/growing companies.

