



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: CMC Statisticians – the backbone from Development to Lifecycle Management

In a Quality by Design context, the CMC Statisticians have a key role in the product Development and through the Lifecycle Management. They can be seen as the backbone that connects all the other CMC departments: Analytical Development, Process Development, Devices, Manufacturing/MSAT, QA, QC and Regulatory Affairs. They define the statistical strategy of the product and help navigate the interactions with the Health Authorities.

Their work in Development is one of the cornerstones of the Control Strategy of the product: Scale Down Model Verification, Process Characterization studies and PAR, CPP determination, Justification of Specifications including Room temperature allowance, Process and Analytical Method validation/comparability, as well as the introduction of a Drug Delivery device.

Once the product becomes commercial, the work continues with the support of the Manufacturing/MSAT for investigations and process improvement using Advanced Analytics tools, as well as tech transfer and continuous support to Development for the new generations of analytical methods and processes.

The presentation will focus on the structure and the ways the CMC statistics team functions and interacts with other departments through Development and Lifecycle Management, while giving some examples of key collaborations/successes.

