



International Alliance for
Biological Standardization

9th Annual IABS Statistics Workshop Applying Statistics and Data Science to Evolving Technical and Regulatory Paradigms

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University of Maryland - IBBR, Rockville, MD, USA

Title : Process Control Strategy, Residual Uncertainty, and the Myth of Fingerprints

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This talk will discuss the role of uncertainty management in the development of biopharmaceutical process control strategies and suggest that articulating the scope, extent, and relevance of CMC uncertainties is central to the technical advocacy supporting regulatory filings, especially in the United States. It will also reflect upon a divergence between execution of statistical analysis and calculation and statistical understanding and communication of relevant uncertainties. The role of cognitive biases arising from speed to market initiatives and other business drivers will be discussed as well, concluding with the open question “Have we got this right?”

