



International Alliance for
Biological Standardization

10th Annual Statistics Workshop: Science & Statistics – Elevating CMC through Partnership

November 12-14, 2024
IBBR, Rockville, USA

Analytical Characterization for Precision Biologics

Developers of biologic products are modernizing analytical control strategies at an amazing pace. Recent advances in analytical characterization provide a foundation for accelerated development and approval for gene therapies, cell therapies, novel vaccines and other pioneering biotherapies.

Control strategies for biologics also depend on a rich legacy of methods and practices established over decades of experience. Functional assays may provide an intuitively direct link to safety or efficacy. However, in some cases older methods such as cell-based potency assays are handicapped by inherently lower precision and accuracy relative to newer methods. The transition to modern methods for analytical characterization can be unfamiliar and complex.

Examples from recent successful submissions will be introduced to illustrate possibilities in this new era, and to stimulate discussion about Quality by Design thinking to bridge the gap between familiar and novel analytical control strategies. In this new paradigm, analytical methods can naturally be managed using a lifecycle approach.

