



International Alliance for
Biological Standardization

**Workshop on Global Harmonization of Specification:
Implementing A Patient-Centric Control Strategy**
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Addressing Uncertainties in Complex Biologics: Enhanced vs. Conventional Approaches

Traditional methods primarily emphasize maintaining process consistency. In contrast, advanced approaches leverage the understanding of structural-function relationships. This presentation will cover:

- The distinction between limits for analytical procedures and Critical Quality Attributes.
- Utilizing product characterization data to establish meaningful limits that ensure safety and efficacy

