



International Alliance for  
Biological Standardization

## Globally Harmonized Specifications: Current State and Future Opportunities

### Summary of 1919 IABS Specifications Workshop

The 2nd IABS Workshop on *Setting Specifications for Biological Products: A Pathway to Harmonization* was held December 2-3, 2019, at the USP Headquarters in Rockville, MD. This followed onto a successful 1st workshop which concentrated on specifications for biosimilars. The 2019 workshop brought industry participants and regulators from vaccines, biotherapeutics, and cell & gene therapies together to share and discuss practices and principles related to establishing specifications. This talk will summarize the technical, regulatory, and business considerations that were identified as key to harmonization. This includes an agreed upon basis for acceptance criteria, a regulatory pathway to harmonization, and some technical and business consequences from lack of harmonization. This will provide the audience with a foundation for discussion throughout the 2023 workshop.

