



International Alliance for
Biological Standardization

**Workshop on Global Harmonization of Specification:
Implementing A Patient-Centric Control Strategy**
June 23-25, 2025
Tokyo, Japan

Title *Science and Risk-based approaches to Specification control: Application to rapid development of Antibody-drug conjugates*

The talk will use the example of rapid development of ADC treatments for critical medical need to consider how specifications can be developed based on scientific principles and prior knowledge, and based on consideration of the overall control strategy. Consideration will be given requirements for small molecule linker/payload and mAb intermediates for ADCs. The talk will reflect on principles developed and published collaboratively across industry, and will include relevant GSK case studies.

