



International Alliance for
Biological Standardization

**Workshop on Global Harmonization of Specification:
Implementing A Patient-Centric Control Strategy**
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Strategies for Defining Specifications in Autologous Cell Therapy Products

In the evolving landscape of autologous cell therapy, the unique challenges of the product variability demand a new approach in setting product specifications. Unlike biologics and small molecules where variability stems from process and analytical variability, autologous cell therapy introduces significant donor variability, which becomes the primary source of overall variability. This presentation explores the fundamental differences between these therapeutic modalities and underscores the limitations of traditional specification frameworks when applied to autologous cell therapies.

A case study focusing on Vector Copy Number (VCN) will be presented, discussing the rationale behind setting two-sided versus one-sided specifications and evaluating the associated clinical safety risks in relation to specification limits.

By adopting a patient-centric approach to setting quality standards, this presentation will demonstrate how ensuring batch quality through deep understanding of product variability can lead to more flexible, safe, and efficacious autologous cell therapies, ultimately benefiting patients.