International Alliance for Biological Standardization

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Case Study in Comparability for an iPSC-Derived, Genome-Edited Cell Therapy Product

During the product development lifecycle, manufacturing changes - such as a new facility introduction, process optimization, or raw material change - may be implemented to improve product quality, supply, or process efficiency. Given that manufacturing changes can pose a potential risk to quality, safety, and efficacy, the execution of comparability studies to assess the effect of these changes on the product is required for both investigational and licensed products. While a framework for evaluating comparability exists for biological products, additional factors may need to be considered for cell and gene therapy products due to the complexity of the product and manufacturing process. Last year, the FDA issued draft guidance for industry to address considerations for manufacturing changes and comparability for cell and gene therapy products. In this session, we present a case study for demonstrating comparability of a new facility introduced during Phase 1 for clinical production of an iPSC-derived, genome-edited cell therapy product, which demonstrates application of these principles.