International Alliance for Biological Standardization

Workshop on Global Harmonization of Specification: Implementing A Patient-Centric Control Strategy

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Title: Specification consideration for CGT products and role of analytics: Challenges and Opportunities

Abstract: Cell therapy products present unique specification challenges that traditional regulatory frameworks like ICH Q6B were not designed to address. Unlike conventional biotechnology products, cell therapies are inherently heterogeneous, living entities with limited shelf-life and dynamic quality attributes that change during storage and transport. This presentation explores the specific analytical challenges faced in cell therapy development at Novo Nordisk.

Key specification challenges include detecting residual iPSCs using sensitive methods like digital droplet PCR, ensuring sterility within limited timeframes, and characterizing complex cell populations through multi-parameter flow cytometry. Traditional 14-day sterility testing is incompatible with short shelf-life products, necessitating rapid microbial methods such as BACT/ALERT and solid phase cytometry that can provide results within hours rather than weeks.

Advanced analytical tools including automated cell counting, flow cytometry, and ddPCR offer enhanced precision, sensitivity, and regulatory compliance while supporting comprehensive quality assessment. However, method validation under time constraints, sample stability issues, and re-source-intensive processes remain significant hurdles. The integration of these cutting-edge analytics is essential for establishing scientifically justified specifications and ensuring patient safety in cell therapy product development and release.