# 2ND INTERNATIONAL CONFERENCE ON CELL SCIENCE AND REGENERATIVE MEDICINE

**David Pérez Cabrera,** Alberto Vazquez Sanz & Irene Zamora Marmol

*Takeda, Madrid, Spain*

## Advancing Identity and Purity Testing Methods for Cellular Therapies

**Abstract:** The design and development of robust identity and purity tests is essential for the safe commercialization of cellular therapies. These analytical methods play a pivotal role in ensuring product consistency during routine quality control testing, reducing unforeseen issues and contributing to long-term operational efficiency. Guidance documents such as ICH Q14 provide a foundation for developing efficient and compliant methods tailored to quality control needs.

Identity and purity tests are conventionally performed as separate assays, often generating greater costs due to elevated consumption of reagents, materials, and time. Combining these assays into a unified method represents a promising avenue to optimize resource utilization, while maintaining precision, reliability, and compliance. Such a strategy requires careful consideration of assay design principles to ensure successful validation and reproducible results during routine application.

To contribute to this evolving analytical landscape, ou our company developed a practical excersice consisting on setting to practice an adequate development strategy for testing cellular therapy products. This effort not only streamlines the testing process but also lays the foundation for a smooth transition to subsequent validation stages.

As part of this initiative, we focused on the characterization of T-cell-based products, with an emphasis on applications in CAR-T therapies. By evaluating the critical specifications required for identity and purity assessments, we established methodological criteria that allow accurate and reproducible characterization of T-cell identity and measure purity levels. These findings enabled us to design a combined analytical approach that meets quality control demands while addressing operational bottlenecks often encountered in separate assay methodologies.

This work exemplifies an innovative step toward advancing state-of-the-art quality control methods for cellular therapies, reinforcing their reliability, efficiency, and applicability in routine manufacturing environments.

**Keywords:** Identity, Purity, Cellular, Therapies, CAR-T, T-Cell

**Biography:** Production Technician at Takeda, part of the Manufacturing Operations team, specializing in biologics within GMS Biologics OpU. With a background in the pharmaceutical industry, my role focuses on ensuring operational excellence in highly regulated production processes, contributing to the quality and sustainability of innovative therapies.