ISBN:
978-1-917892-15-5

Global Summit on
Materials Science and Engineering

July 21-22, 2025 | Paris, France

Pelin KILIC[1,2*], Sema KARABUDAK[3,4], Begum COSAR[2,5], Busra Nigar SAVRAN[2,6], Merve YALCIN[7]

[1] *Department of Stem Cells and Regenerative Medicine, Stem Cell Institute, Ankara University, Ankara, Türkiye*
[2] *HücreCELL® Biotechnology Development and Commerce, Inc., Ankara, Türkiye*
[3] *Department of Medical Genetics, Medical Faculty, Ankara Yıldırım Beyazıt University, 06800 Ankara, Türkiye*
[4] *Central Research Laboratory Research and Application Center, Ankara Yıldırım Beyazıt University, Ankara, Türkiye*
[5] *Department of Molecular Biology and Genetics, Institute of Science, Başkent University, Ankara, Türkiye*
[6] *Graduate School of Natural and Applied Scinces/Biology, Gazi University Ankara, Türkiye*
[7] *School of Pharmacy English Program, Ankara University, Ankara, Türkiye*

Ensuring quality and consistency in cellular therapeutics: analytical insights from residual protein assessment

Abstract: The reliability and safety of cell-based therapies hinge on rigorous quality control measures, particularly in identifying and mitigating residual impurities that may impact therapeutic performance. Residual proteins originating from culture systems, enzymatic treatments, and purification processes pose significant risks, potentially triggering immunogenic responses, altering cellular functionality, or compromising batch-to-batch consistency. As regenerative medicine advances, ensuring a standardized and analytically robust approach to impurity detection is crucial for regulatory compliance and clinical success. This presentation takes a broad analytical perspective on quality assessment in cell-based therapy manufacturing, highlighting key methodologies for impurity detection with a focus on electrophoretic and chromatographic techniques. By drawing from our recent study on sodium dodecyl sulfate-polyacrylamide gel electrophoresis (SDS-PAGE)-based residual trypsin and trypsin inhibitor analyses in bone marrow-derived mesenchymal stem/stromal cell (BM-MSC) products,

the speech examines the practical applications, advantages, and limitations of these approaches within the broader quality control (QC) framework. Beyond method selection, the critical role of residual protein analysis in assessing stem cell functionality, immunogenicity, and long-term therapeutic viability is explored. Conclusively, by integrating targeted analytical strategies into standard workflows, manufacturers can improve process reproducibility, enhance product safety, and meet evolving regulatory expectations for cell-based therapies. This talk provides a research-driven and practical outlook on the evolving landscape of quality assurance (QA) in regenerative and restorative medicine applications, emphasizing the need for comprehensive analytical frameworks to support the widespread clinical adoption of cellular therapeutics.

Keywords: cellular therapeutics, chromatography, electrophoresis, mesenchymal stem/stromal cells (MSCs), residual protein, sodium dodecyl sulfate-polyacrylamide gel electrophoresis (SDS-PAGE).

Biography: Born in Ankara in 1978, Dr. Pelin Kılıç received her pharmacy and pharmacology master's degrees from Gazi University and her doctorate in forensic toxicology from Ankara University. She researched gene technology at INSERM, France, and shaped Türkiye's advanced therapy regulations as a Turkish Medicines and Medical Devices Agency (TİTCK) government officer (2004–2016). An academic since 2017, she specializes in stem cell and regenerative medicine. As also the founder of HücreCELL® Biotechnology, Inc., she mentors young scientists. Her R&D covers iPSC-based models for diabetes/associated cardiovascular complications, extracellular vesicle-defined biosensors for cancer screening, and upstream/downstream process engineering of cellular therapeutics.