Bioanalytical quality control tool for clinical-grade stem and progenitor cells

Stem cells and their products hold a great promise for regenerative medicine, bioindustry or tissue engineering. However, their use is limited by lack of reliable and quantitative quality control (QC) markers that would reveal phenotypic shifts before they manifest morphologically and functionally. Recently,



we have introduced a bioanalytical method that overcomes limitations of established molecular and genetic QC markers in clinical-grade stem cell cultures. Our method combines the Whole Cell MALDI-TOF Mass Spectrometry coupled with chemometric methods common in bioanalytical chemistry. Spectral profiles analyzed by multivariate classification and machine learning can reveal minute phenotypic shifts in various cell culture scenarios with high sensitivity and specificity. In summary, we aim to improve safety of stem cells and their products by introducing our method to cell culture QC schemes.

Application

• Quality control by mass spectrometry-based profiling of stem cells and progenitors

Competitive Advantage

- Large-scale
- Low-cost
- Instrumentation-independent

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Market Assessment

Cell culture laboratories and small and medium-sized enterprises involved in development of cell therapy and regeneration medicine
Specifically regulated market segment (by SUKL – State Institute for Drug Control, regulatory authority on the national level for cellbased applications and advanced therapy medicinal products).

IP Status

• Key intellectual assets have currently been the know-how (analytical and statistical methods, reagents etc.) and can be only provided under the confidentiality agreement

Needs

- Assistance with translation product development
- Provide us "business thinking"
- Assistance with regulatory aspects
- Mediating communication with industrial partners



