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Enhanced quality small molecules as ancillary materials

Using small molecules in cell therapy development

Small molecules can be used throughout the development of iPS-derived cell therapies, in much the same way as protein growth factors or genetic manipulation, for reprogramming, maintenance and differentiation. However, small molecules offer several advantages over these techniques for the manufacture of stem cell-derived cell therapies!

Cell permeable
Enables easy probe delivery

Synthetically manufactured
Low lot-to-lot variability, high purity and scalability

Temporal control
Easy addition or removal via media exchange

Good value
Cost effective compared with proteins and viral vectors

Tunable
Effects are concentration dependent

Using small molecules in cell therapy development

Small molecules are widely available, but choosing the right reagent supplier can be difficult, because it is not always clear which guidelines providers are following with respect to the manufacture of small molecules as ancillary reagents or raw materials for cell therapy development.

Although standard research reagents (research use only or RUO) are suitable for the early stages of cell therapy protocol development, using enhanced quality materials early in the manufacturing and testing phases avoids making costly changes later on.

The closer a cell therapy approaches to the clinic, the more expensive and difficult it becomes to alter reagents and components. By switching early in the research cycle to enhanced quality small molecules, such as Ancillary Material (AM) Grade products, you can reduce the risk, time, and cost associated with revalidating assays and protocols for regulatory compliance.

Risk | **Time** | **Cost associated**

Benefits of enhanced quality ancillary reagents

Manufacturing controls

QC testing

Documentation

Benefits for your process

Process consistency

Risk of batch failure

Time and cost

Regulatory compliance

Benefits to the patient

Safety

Time to develop new therapies

What are AM Grade reagents?

Bio-Techne's AM Grade products are manufactured with additional levels of control compared to standard research reagents, ensuring their suitability for the onward manufacture of your cell therapy. The production follows ISO 20399:2022, a set of guidelines to improve the consistency and quality of raw materials used in the production of cell and gene therapies.

The AM Grade product range offers an economical and time efficient solution to providing ancillary reagents/raw materials suitable for cell-based therapies transitioning to the clinic, which retain some of the key benefits of cGMP including:

Animal-free production (Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE) free certification)

Segregated manufacturing area to reduce cross-contamination risk

Enhanced quality control testing including bioburden and endotoxin of final products

Starting material traceability

ISO-7 clean room

Controlled manufacturing zone

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