CELL & GENE THERAPY INSIGHTS

RAW AND STARTING MATERIALS:
TROUBLESHOOTING SUPPLY, MANAGEMENT & OPTIMIZATION ISSUES

SPOTLIGHT

Broadly speaking, starting materials are key building blocks that form the foundation of the therapeutic product, whereas raw materials are typically reagents and other ancillary materials used within the manufacturing process.

FOREWORD

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Attention to raw and starting materials used in the production of Advanced Therapeutic Medicinal Products (ATMPs) grows substantially with each successive year. This makes intuitive sense as the field continues to mature and more products approach or enter the commercial market. Companies have focused their development activities on clinical proof of concept and manufacturing process robustness with an eye toward establishing this new treatment modality. Now that more products have de-risked the technology and generated

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initial market penetration, manufacturers are establishing greater control across all aspects of their supply chains.

Succinctly defining raw materials and starting materials can be challenging, as it heavily depends on what type of product is being produced. For instance, plasmid DNA is usually classified as a raw material if the viral vector being produced is used as the starting material in a gene-modified cellular therapy, but is a starting material if the vector is the finished product, as is the case for in vivo gene therapies. Broadly speaking and solely for the purpose of establishing a baseline definition, starting materials are key building blocks which form the foundation of the therapeutic product (e.g., viral vector and patient/donor cells), whereas raw materials are typically reagents (e.g., media, serum, growth factors, stimulation beads) and other ancillary materials used within the manufacturing process. Out of scope would be finished products as well as general consumables such as tubing sets, culture bags, pipettes, and so forth.

The risk imposed from raw and starting materials on the quality and supply of the finished product is heavily influenced by numerous factors, for instance how the material is produced (e.g., if it is human-derived), the grade (e.g., Research, High-Quality, GMP), and the availability of suppliers (e.g., sole-sourced, single-sourced, or multiple sources). This level of risk is impacted by the level of characterization available directly from suppliers, and requirements for additional characterization and qualification increase as the therapeutic program progresses through product development. Regulators factor these considerations in when determining the expected level of control for any given material.

This Spotlight edition of Cell & Gene Therapy Insights explores a broad range of aspects of raw and starting materials for ATMPs. We hope sharing experiences from numerous innovators will benefit the entire industry as the field continues to mature.

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