MATERIAL CONSIDERATIONS FOR CELL & GENE THERAPY PRODUCTS

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Cell & Gene Therapies use novel critical materials where we have limited knowledge and face challenges in development and manufacturing due to their variability and unknown quality attributes. As the field is fairly new, we are facing challenges with research grade materials which are not well understood, and new suppliers who are not entirely familiar with requirements for pharmaceutical development and manufacturing. Material and supplier selection decisions early in the development of ATMPs are crucial and can impact product quality and patient supply. The measures taken to establish appropriate controls at early stages enable use of the same raw materials in all phases of the product development reducing comparability and/or regulatory risks. Many of the materials used for ATMP production are manufactured by suppliers that have limited experience with GMP biopharmaceutical manufacturing. As a result, there can be misalignment between supplier capabilities and ATMP developer expectations regarding technical, supply, quality, and regulatory compliance requirements for biomanufacturing.

This talk will address the considerations for a science and risk-based approach to material selection and qualification, including considerations for aligning internally and externally on definitions and implications of material classification and material grades.