The Commercialization of Cell and Gene Therapies – a Perspective from the Analytical Quality Control function

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Cell and Gene Therapies (CGTs) can be highly curative. The response rate for advanced therapy medicinal products like CGTs is unprecedented. The Lonza New Product Introduction and Lifecycle process for CGTs enables a streamlined product development and allows to achieve a robust commercially viable manufacturing and quality control process. The key modalities in cell and gene therapies each present unique challenges and opportunities also leading to a need for different analytical method requirements. Challenges in CGTs include accelerated clinical development which requires faster timelines for Chemistry, Manufacturing and Controls (CMC) thus faster timelines for analytical development as well. Manufacturing comparability evidence must be supported by fit for purpose analytical methods and linked to clinical evidence. This specifically applies for potency assay methods mimicking and confirming clinical outcomes . Short shelf life of the products or immediate medical need impose specific challenges to analytical methods to be fast and efficient, respectively interim read-out of results may be needed for fast track product release. In this presentation, a general approach to development, commercialization, industrialization, and delivery in line with cGMP is outlined from an analytical quality control perspective.