Robust and reliable analytical methods: critical requirements for industrialization of cell and gene therapies

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Over the last few decades, a wide range of cell and gene therapies have emerged including the viral vector-based gene therapies, autologous and allogenic cell therapies. These therapies offer potential solutions to treat devastating diseases such as cancer, diabetes, or neurodegenerative disorders. In order for these therapies to have widespread therapeutic significance and become readily available, it is necessary to address multiple challenges associated with the Chemistry, Manufacturing and Controls (CMC) strategy including establishment of a phase appropriate manufacturing process, sampling plan, process analytics, and product release testing and logistics. Development of phase-appropriate, robust and reliable analytical methods is the primary requirement for development of robust and commercially viable manufacturing processes. A well-designed testing strategy is required to ensure adequate characterization of the final product (and intermediate materials generated throughout the process) can be achieved through implementation of reliable analytical methods as in-process monitoring, in process decision making assay or release testing during the manufacturing campaign. Here, we are going to review some of the current challenges associated with the development of appropriate analytical methods for cell and gene therapies and particularly highlight our approach, at Lonza, towards the development of robust and reliable analytical methods to properly test and characterize cell and gene therapy products. Using a cell therapy application as a case study, we will specifically highlight the testing strategy and our rationale towards choice of analytical methods implemented in the manufacturing process while ensuring reliability and robustness of the assay.