BACK TO THE FUTURE: A BACK AND FORTH MANUFACTURING PROCESS JOURNEY FROM MONOCLONAL ANTIBODIES TO VIRAL VECTORS FOR CELL AND GENE THERAPY

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The advent of new gene and cell therapies brings high promises to meet unmet medical needs. But, this also raises questions about how to produce these therapies cost effectively at scale. More specifically, producing enough high quality viral vector is key. Many early production and purification processes relied on techniques that are challenging to scale up, or are not commercially available at larger scales and sometimes even not compliant with cGMP. Scalable production and purification techniques from process development to cGMP compliant commercial manufacturing are therefore required. This feels like travelling back in time when the same challenges arose for the development of monoclonal antibodies. So instead of re-inventing the wheel, can we leverage lessons learnt from this past experience? Considering that processes for both mAbs and viral vectors include similar steps in term of cell culture, harvest, purification and formulation, the technologies developed and optimized for mAb manufacturing should therefore be applicable to viral vector processes. Here we will discuss the process similarities and differences for mAbs on one hand and adeno-associated viruses and lentiviruses on the other hand, focusing on gaps identified in developing process platforms for the production and purification of viral vectors. We will show how even the most recent advances in continuous bioprocessing for mAbs can be implemented quickly for viral vectors and the subsequent benefits generated in term of process productivity and economics.