

ECONOMICS OF LENTIVIRAL VECTOR PROCESSES

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With the recent market approvals of autologous CAR T-cell therapies, lentiviral vectors (LVs) have been in the spotlight as a potential bottleneck to their already hindered scalability. Unstable at room temperature, LVs are routinely manufactured in multi-layered vessels using transient transfection methods. However these traditional processes are not sufficiently scalable or cost-effective for future anticipated demands. This poster discusses five different cell culture platforms that have been reported to deliver LVs: the 10-layer vessels, hollow fibre bioreactors, fixed bed bioreactors, rocking motion bioreactors in microcarrier mode and single-use bioreactors in suspension mode. These are compared from a process economics perspective across a range of scenarios that include different titre and dose size scenarios. The use of LVs for two therapeutic approaches are explored, namely for CAR T-cell therapies and haematopoietic stem cell/gene therapies. Costs of goods (COG) trends are described for a range of demands, target process parameters are identified and uncertainty analysis is carried out to capture the impact of variations in titre on the performance of each type of process.