

## A DUAL PLATFORM REVOLUTIONIZING GENE THERAPY MANUFACTURING

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Advanced therapies enable for many indications with no current treatment a significant improvement in quality of life and in some cases a chance at life altogether. The commercialization of those breakthrough therapies rely on manufacturing technologies primary developed for the mAbs industry. Indeed, the commercialization of mAb products was accompanied by technology advances reaching high-capacity and cost-effective processes within integrated and continuous solutions. Nevertheless, in contrast with mAbs where the annual demand (in the US) can be estimated between hundreds of grams to hundreds of kilograms, GT products show an annual demand variability of over 7 logs. Currently used technologies present some limitations in reaching the capacity required by high-demand GT indications resulting in process scale-out and related overall performance decrease. As GT developers often endeavor to target numerous indications, the significant variability in annual demand has pushed them to adopt technologies depending on the types of applications, rather than adopting a single flexible technology. As lessons learn from the mAbs industry the development of a flexible technology accommodating most process requirements adapted to GT products could facilitate viral vector manufacturing while accelerating the availability of advanced therapies at reduced costs.

As a technology innovator Univercells Technologies is always willing to develop and improve its manufacturing solutions to tackle the challenges encountered by advanced therapy developers throughout their development and commercialization steps (scale-up being one of the biggest challenges). Based on its bioprocessing expertise and understanding of GT production drawbacks our teams have deployed solutions integrating the principles of intensification and chaining within automated platforms to offer access to continuous manufacturing. The structured fixed-bed technology featured in our technologies have demonstrated to enable a seamless scalability across scales to facilitate the shift from development to commercialization. Recent studies performed in collaboration with scale-X™ users have demonstrated an encouraging possibility to decouple process development from technology selection thanks to a flexible technology accommodating the growth of both adherent and suspension cell lines. The obtained results show that the already proven benefits of our integrated and intensified structured fixed-bed technologies are also applicable to suspension-based processes with higher viral productivity and reduced CoGs.

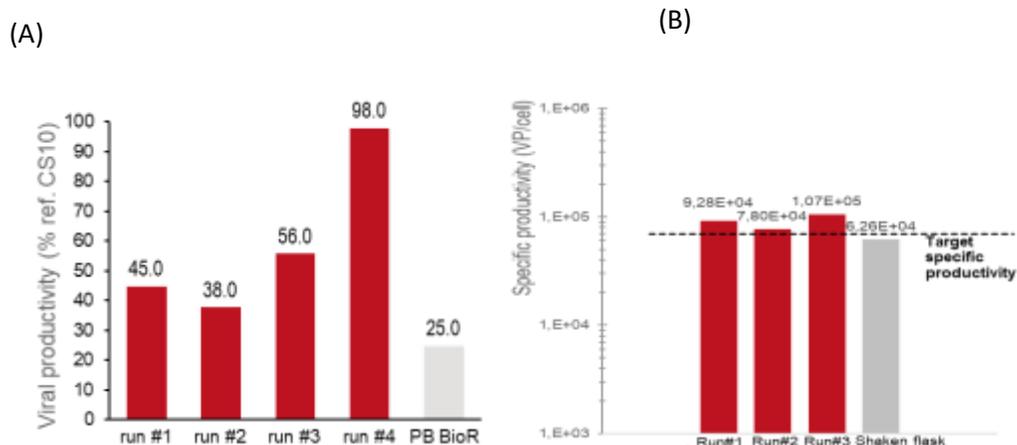


Figure 1 – Viral productivities experimental results obtained with direct process transfer from alternative technologies and scale-X hydro structured fixed-bed bioreactors (A) Adherent-based process with HEK293 cells for AAV production (B) Suspension-based process with HEK293 cells adapted to suspension for Adenovirus production.