

## **INTEGRATED & CONTINUOUS PROCESSING: A PROVEN SOLUTION TO TACKLE GENE THERAPY MANUFACTURING CHALLENGES**

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Over the last four decades, the monoclonal antibody (mAb) industry has seen several evolutions. Working toward a continuous approach, mAb production processes were redefined to reduce manufacturing footprint and increase the overall productivity and reducing manufacturing COGs. This effort initially started with increasing upstream productivity before moving to overcoming subsequent midstream and downstream processing challenges. These unit operations would eventually be combined into continuous and automated manufacturing platforms.

With so much progress made in mAb production, the biotherapeutics industry is now seeking answers for newer modalities like gene therapies (GTs). Though demand for manufacturing capacity for gene therapies continues to increase, these associated manufacturing processes are yet to catch up with the manufacturing needs. Gene therapy manufacture relies in non-scalable technologies or legacy technologies inherited from other modalities (e.g. flatware, STR, packed bed reactors), constraining developers to eventually scale-out their process rather than scale-up. Running parallel operations increases the overall volume and footprint needed to achieve commercial production scales.

Recent technology innovation offers a paradigm shift towards integrated continuous manufacture of viral vectors with next generation equipment purposefully designed to overcome such challenges. These technologies apply the principles of process intensification and process integration and automation to enable integrated continuous processing and redefine scalability in GT manufacture.

This presentation will show how leveraging lessons learned from the mAbs industry enable to reach capacity increase and manufacture acceleration for GTs. Inspired by the continuous processing approach applied to mAbs, a novel technology tackling GT challenges was designed. Case studies demonstrating the experimental and economic performance of applying integrated and continuous processing to GT manufacture.