

## **INTEGRATED UPSTREAM AND MIDSTREAM PROCESSING WITH SCALABLE PRE-CONFIGURED SINGLE-USE ASSEMBLIES FOR ACCELERATED COMMERCIAL REACH**

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The growth of single-use technologies (SUT) has revolutionized the bioprocess industry. The implementation of such technologies was motivated by a substantial reduction in processing time and operational costs compared to their stainless-steel counterparts. Integrated within automated platforms such as the NevoLine™ Upstream, SUT reveal their full potential by offering an increased flexibility and supporting continuous processing. With 100s of different SU configurations the NevoLine platform can accommodate most upstream and midstream processes by integrating four unit-operations in a single manufacturing solution. Cell culture and viral production steps lie in scalable SU bioreactors (SUBs) available in various sizes optimal for process development, as well as clinical and commercial GMP production of viral vaccines, viral vectors for gene therapy and other emerging applications. The SUBs are featured in a range of scale-down automated manufacturing systems that ease scalability. The improved sterility assurance and controls offered by SUT enable predictable batch-to-batch performances and release. The pre-gamma irradiated SU assemblies integrated in Univercells Technologies' manufacturing systems open the door to ready-to-use solutions reducing installation time and easing sterile continuous processing.

This study will demonstrate how the NevoLine Upstream integrated platform relying on SU assemblies can support continuous processing and accelerate commercial reach.

It will focus on the following points:

- Intensified cell growth and viral production in the SU scale-X™ bioreactor with up to 100-times increase in titer compared to traditional technologies with experimental results in various gene therapy and vaccine applications.
- Bioreactor characterization with scalability demonstration from scale-X hydro 2.4 m<sup>2</sup> to nitro 200 m<sup>2</sup> cell growth surface by maintaining fluid flow homogeneity, gradient, and volume to surface ratio across scales. Homogeneity within the fixed-bed will be demonstrated by sampling experiments with confident results. The scalability will be demonstrated by similar cell growth and viral titers per m<sup>2</sup> of growth surface profiles across scales.
- Increased process flexibility at commercial scale with the integrated and automated NevoLine Upstream platform adapted to multi-product facilities and variability in production capacity demand.
- A significant reduction in operational footprint (up to 3-times) enabled by intensified and integrated SU assemblies.