



Intensified Biomanufacturing Technologies

Building capacity for AAV and lentiviral vector production

scale-X™ NevoLine™



UNIVERCELLS

scale-X™

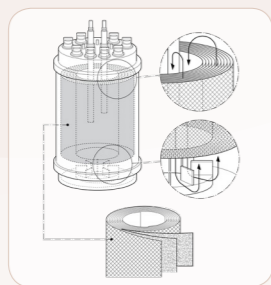
ENHANCED UPSTREAM PROCESSING OF VIRAL VECTORS

A novel single-use, high-density bioreactor delivering reproducible and scalable production.

Intensified fixed-bed bioreactor

The scale-X bioreactor features a novel structured fixed-bed design alternating treated spiral-wound micro-fabric and spacer netting for:

- » Rapid and homogeneous cell entrapment;
- » Homogeneous media flow and nutrients availability.



[hydro]

[2.4 m²]



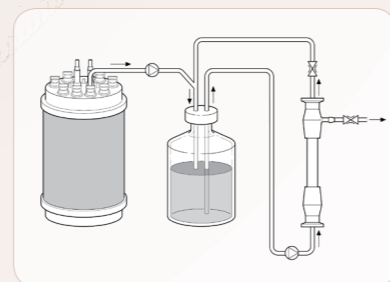
[carbo]

[10-30 m²]



[nitro]

[200-600 m²]



Viral production and harvest

The scale-X fixed-bed bioreactor is chained with in-line product concentration for intensified cell culture and viral production delivering a concentrated harvest.

Scalable by design

- » Constant linear velocity of fluids and homogeneous cell distribution throughout the fixed-bed ensure reproducible performance at all scales;
- » Comprehensive portfolio features solutions for R&D, clinical and commercial scale production.

Scalable technology

- » Seamless transitions through process development, clinical validation and commercial manufacture

High productivity

- » Offering the highest throughput per cleanroom surface compared with currently available technologies

Cost-effective

- » Significant operating costs savings across the different stages of the product lifecycle

NevoLine™

NEXT EVOLUTION OF MANUFACTURING TECHNOLOGIES

INTEGRATED & COST-EFFECTIVE VIRAL VECTOR PRODUCTION

Combining process intensification, automation and chaining to reduce footprint, capital and operational costs.

Formulation

Integrated formulation sequence for a complete solution from cell culture to drug substance preparation.



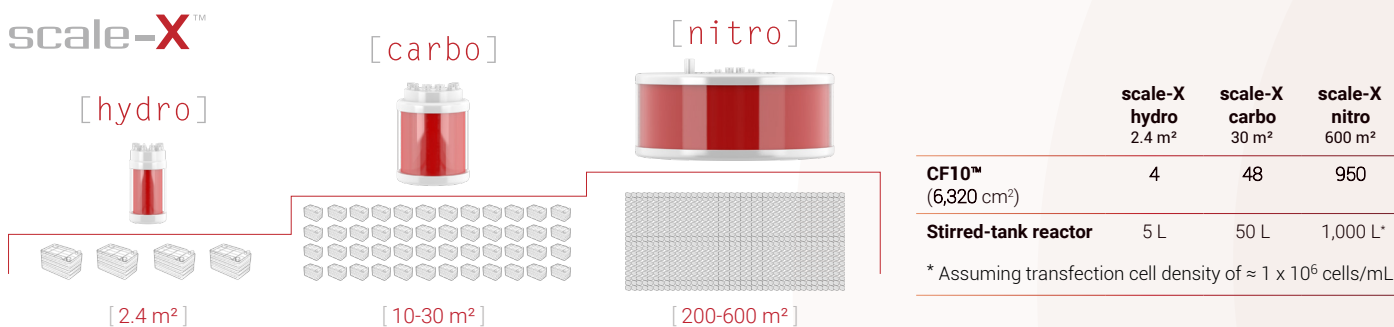
Purification

Integrated and automated purification system using multicolumn chromatography to:

- » Increase resin utilization;
- » Reduce processing times;
- » Minimize surge tanks size.

A scalable roadmap to commercial success

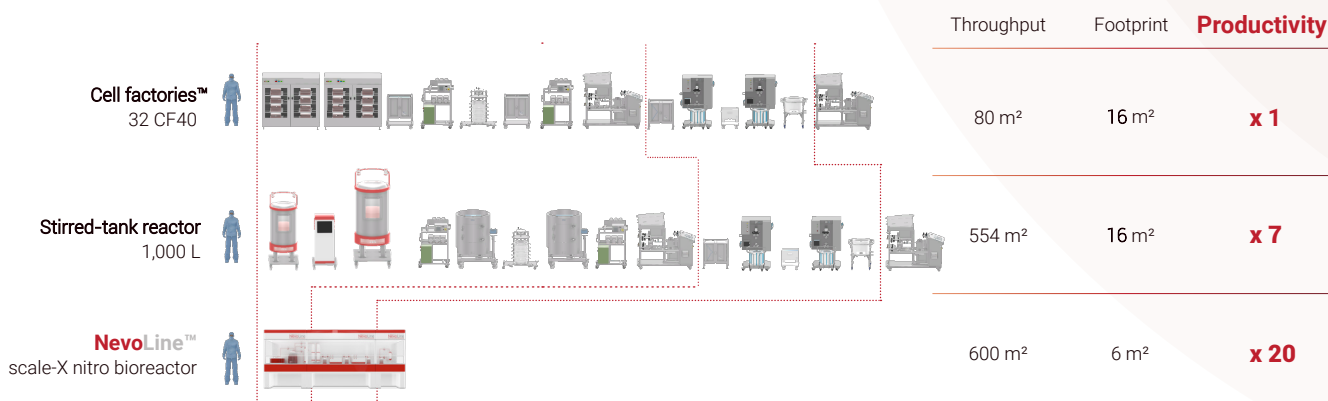
The scale-X fixed-bed bioreactor portfolio enables a seamless transition from R&D to clinical development and commercial manufacture while minimizing process changes.



High capacity over a low footprint

The NevoLine platform features intensified manufacturing chained into a continuous, automated process to drastically decrease facility footprint and deliver:

- A scalable solution with high productivity
 - » **Up to 20-fold higher productivity (vg/m² of cleanroom) compared to existing technologies**
- An “all in one” solution compatible with modular facility design
 - » **Rapid deployment in a POD or modular format in new or existing facility**



Streamlined development with drastic savings

The NevoLine production platform drastically decreases COGs through reduction of key consumables and reagents, delivering significant savings for commercial-scale manufacture.



Assumptions

Extracellular product
Annual AAV demand: 1E+18vg/year

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