

THE NEVOLINE™ MANUFACTURING SYSTEM: INTENSIFICATION & INTEGRATION OF UPSTREAM AND DOWNSTREAM PROCESSING IN A LOW-FOOTPRINT, AUTOMATED PLATFORM FOR VIRAL PRODUCTION

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The world is facing an under-supply of some key vaccines due to poor synergies between growing market demands and aging production models.

In this light, we have developed a proof of concept of a vaccine manufacturing platform aiming at increasing availability and affordability of vaccines - the NevoLine™ system.

This simulated continuous and automated platform integrates both USP1 and DSP2 processes and is encapsulated into an isolator, making it a self-contained production unit (6m²). The technology relies on a single-use, high-density fixed-bed bioreactor operated in perfusion chained with downstream filtration, clarification and polishing steps to (a) decrease batch time, (b) reduce equipment utilization, (c) optimize utilities consumption and (d) intensify operations. By optimizing single-use technologies we are able to drastically reduce CAPEX³, CoGs⁴ and footprint and increase production capacity. Such manufacturing platform can easily be implemented into flexible facilities with simplified infrastructure, increasing adaptability in production and capacity for record time-to-market.

This study will present the platform proof of concept on Vero line and trivalent inactivated polio vaccine (sIPV) production, achieving low CoGs (0,28\$/dose for a trivalent sIPV) and large capacity. The presentation will feature the description of engineering development, but also results of cell growth, infections and product quality, as well as a description of the CAPEX, CoGS and capacity calculations. This manufacturing platform is undergoing sIPV process scale-up and pre-clinical bulk production.

The NevoLine system is expected to produce any type of viral vaccine at a very low cost and large capacities to face global health challenges.

¹ Upstream

² Downstream

³ Capital expenditure

⁴ Cost of goods