

NevoLine™ Biomanufacturing System

Next Evolution of Viral Production





INTENSIFIED & AUTOMATED VIRAL PRODUCTION SYSTEM IN 10M2

Containment & Safety

- » Low-footprint process enabling integration in biosafety cabinets or isolators
- » Automated process reducing manual operations
- » Closed system ensuring process and environment safety

Downstream Module

Intensified streamlined purification

- » Harvest clarification
- » In-line chromatography

Additional Modules for Inactivation, Aliquoting, etc

Automated operations in a controlled environment

» Based on process needs

Nevolune Nevolune Secale production

FEATURES

Applications

- » Viral vaccines
- » Oncolytic viruses
- » Viral vectors
- » Pilot to commercial-scale production

Dimensions $(L \times W \times H)$

- » NevoLine: 6650 x 1610 x 2367 mm
- **»** Upstream & Downstream: 2158 x 1610 x 2367 mm
- **»** Additional: 1533 x 1610 x 2367 mm

Integration into:

- » Greenfield facility construction
- » Existing facility revamping
- » Container-size POD for rapid deployment

Upstream Module

Intensified cell culture & viral production, delivering concentrated harvest

- » High-density scale-X™ fixed-bed bioreactor for cell culture & viral production
- » Chained with in-line product concentration

BENEFITS

Cost-effective Production

- » Reduced classified area footprint & simplified infrastructure
- » Low capital investment
- » Low operational expenditures

Automated Operations

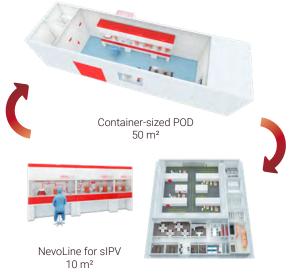
- » Virus containment
- » Environment and operators safety

Rapid Deployment

- » Fast implementation in new or existing facility
- » Reduced time-to-market
- » Adaptable to epidemic preparedness approaches

Case study: trivalent sIPV production in a NevoLine-based facility

4 NevoLine systems delivering over 50M doses of trivalent inactivated polio vaccine annually



POD-based facility 1,500 m²

Estimated CAPEX: \$ 20M

POD-based facility with 4 NevoLine systems

Estimated CoGs: < \$ 0.30/dose

Including upstream, downstream and viral inactivation

Estimated Capacity: 50M doses/y

Each NevoLine system delivers 577,000 doses/batch of trivalent sIPV, 22 batches/year

Nevoline reduces facility footprint & investment requirements

NevoLine		Single-Use (SU)	Stainless Steel (SS)
(60	4x NevoLine 00 m² biorecators) 50M doses/y	5x750 L bioreactors 54M doses/y	6x750 L bioreactors 54M doses/y
CAPEX (USD M)	NevoLine NevoLine		~ 20
	SU		~ 50
	SS		~ 200
Footprint (m²)	NevoLine		1,500 m ²
	SU		4,000 m ²
	SS		~ 10,000 m ²
Utilities (USD/run)	NevoLine		5,400
	SU		35,500
	SS		75,000
CoGs (/dose)	NevoLine		< \$ 0.30
	SU		\$ 0.6
	SS		\$ 1.2-1.5

Assumptions

Calculations: BioSolve. Facilities built from scratch, utilized at capacity.

Purifications yield : NevoLine 57%, SU & SS 45%. Batches/year : NevoLine : 22, SU : 20, SS : 16.