



## Viral Vector Platform in POD Cleanroom System



### *Scale through flexibility*

Pall's viral vector equipment, process development (PD) expertise, and production know-how address industry's most pressing challenges. Coupled with G-CON's prefabricated cleanroom PODs, this collaboration delivers a scalable platform in a flexible facility that is rapidly deployable and able to be repurposed to respond to changing requirements.

Current viral vector manufacturing methods are inefficient in terms of scale, yield and reproducibility. Regulatory and manufacturing economics require increased flexibility that traditional facility architecture cannot provide. Additionally, conventional approaches for capital projects are taking too long to complete, where time to market is a key driver for success.

### *Established Viral Vector Platform*

Pall's viral vector platform is well known to the gene therapy industry. It is a complete end-to-end process that is well integrated, consisting of both upstream and downstream technology.

## Complete End-to-End Scalable Viral Vector Solution

**Upstream:** Xpansion® bioreactor, iCELLis® bioreactor

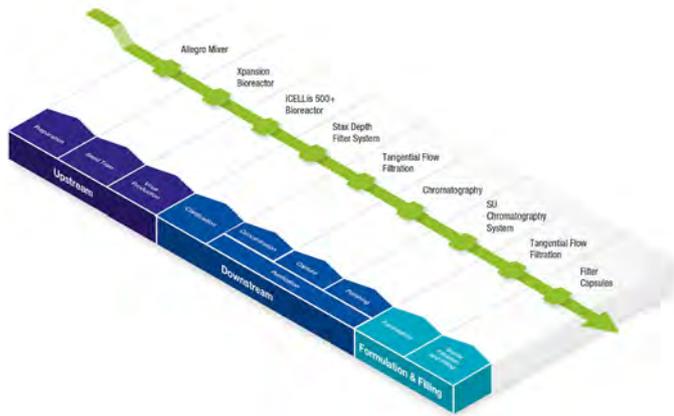
**Clarification:** Stax™ depth filter system

**Purification/Concentration:** Multiple modes of chromatography, including Mustang® S/Q membrane. Tangential flow filtration, including Cadence® inline concentrator

**Sterile Filtration:** Allegro MVP single-use system, Kleenpak™ capsules with Supor® membrane

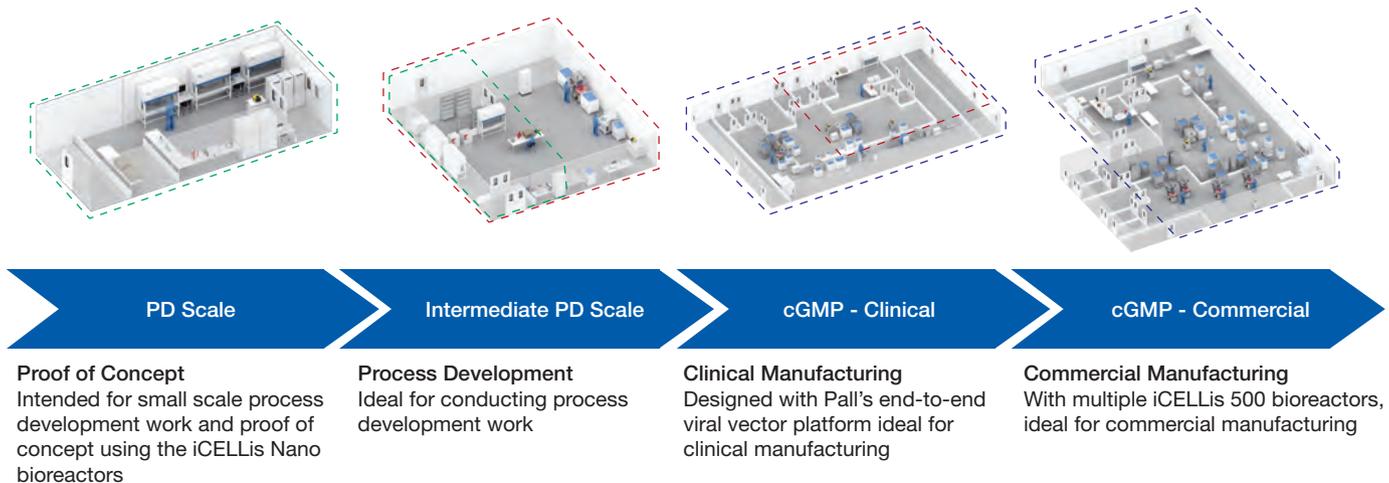
**Figure 1**

*Pall's end-to-end viral vector solution*



**Figure 2**

*Complete flexibility to scale your process*



## Proven Success

Through our Accelerator<sup>sm</sup> process development services, Pall has developed 17 viral vector processes for 11 clients. Pall's viral vector platform, versus conventional methods such as a multi-layered flasks platform, can lead to a 40-50% decrease in operating expenditure (OPEX), a 50% reduction in capital expenditure (CAPEX), and a 66% reduction in facility footprint when reaching manufacturing scale. As an example, our iCELLis fixed bed bioreactor allows for seeding densities as low as 3,000 cells/cm<sup>2</sup>, which equates to approximately 800 multi-layered vessels. In turn, footprint is significantly reduced, and upstream (USP) and downstream processing (DSP) cost/dose are lower. Additionally, Pall's platform leads to significant reduction of labor and USP consumables versus a multi-layered vessel.

## Prefabricated Cleanroom Solution

This process is even more turnkey/complete by now being offered inside a G-CON prefabricated cleanroom POD system. PODs can be manufactured simultaneous to the production of the process equipment, shrinking the time to have the facility ready. They also provide the flexibility to scale out your facility, whether you are starting with a smaller footprint or are building for cGMP operations.

## Benefits

Cleanroom PODs are configured to accommodate all Pall process equipment in an ergonomic and lean manner, and are designed to meet FDA and EU regulatory requirements, as well as customer specific qualification requirements. PODs are purchased like a piece of equipment and require minimal connection to the host facility.

## Operational Benefits

- ▶ Time – customers can receive a complete viral vector platform in 10 months – fully fitted POD, delivered and validated.
- ▶ Facility flexibility – PODs can be moved, reconfigured or repurposed.
- ▶ Scalability – Additional PODs can be added or taken away as demand requires.
- ▶ Containment – The PODs are equipped with dedicated air handling units, allowing them to be decommissioned without affecting the rest of the facility.
- ▶ Biological safety level (BSL) 2 areas have dedicated air handlers for compliance that allow for vapor hydrogen peroxide (VHP) decontamination during campaign turnover.
- ▶ Pall equipment reduces batch failures and issues in scaling up to commercial production, improving process reliability.
- ▶ PODs can provide unidirectional flow, single pass air, doors interlocks, pass-throughs, utility and gas services, process piping, multiple levels of automation, multiple interior surface options, etc.
- ▶ The ISO classification of the POD will depend on the application. Typically, PODs are built for ISO 5, 6, 7 or 8, but have also supported CNC (controlled not classified) space.
- ▶ PD & Intermediate Scale PODs: deliver USP/DSP capabilities and facility aimed for process development and some pre-clinical manufacturing at an affordable price that can be scaled out to a cGMP facility.
- ▶ cGMP
  - Clinical Scale PODs: Fully integrated end-to-end USP/DSP equipment and facility designed for clinical manufacturing.
  - Commercial Scale PODs: Additional upstream capabilities with multiple iCELLis bioreactors to accommodate commercial manufacturing.

## Implementation Benefits

- ▶ Reduced time to market with integrated process development, basic facility design, detailed design executed seamlessly and in parallel.
- ▶ Access to Pall's Accelerator PD services for process optimization and scale-up.
- ▶ Access to Pall's engineering and solution capability to scale the PD data into a turnkey production solution.
- ▶ Reduced infrastructure planning.
- ▶ Minimal management of onsite construction.
- ▶ No delays for construction permitting.
- ▶ No need for laydown space for construction materials at the customer site.
- ▶ Predictable timelines with known materials and cost.
- ▶ Minimal time lost for logistics, training, union concerns, after hours limitations, etc.
- ▶ Prefabricated PODs are built offsite while the host facility is built or renovated.
- ▶ PODs are built in a controlled factory environment; low execution risk.
- ▶ PODs are built to accommodate Pall equipment placement, utility and electrical requirements.
- ▶ Platform timeline allows capital decision to be delayed until months before facility is needed.
- ▶ Access to Pall's bioprocess engineering and application specialists for equipment installation/troubleshooting and platform training.

## Project Workflow

**Step 0 (PD – optional):** Pall's Accelerator process development team optimizes and scales up customer's process into Pall's viral vector platform.

**Step 1 (Review):** Pall's engineering team and G-CON work with the customer to provide a combined solution by reviewing the project URS and mass balance. Ideally, the standard platform design should be utilized to minimize overall lead time.

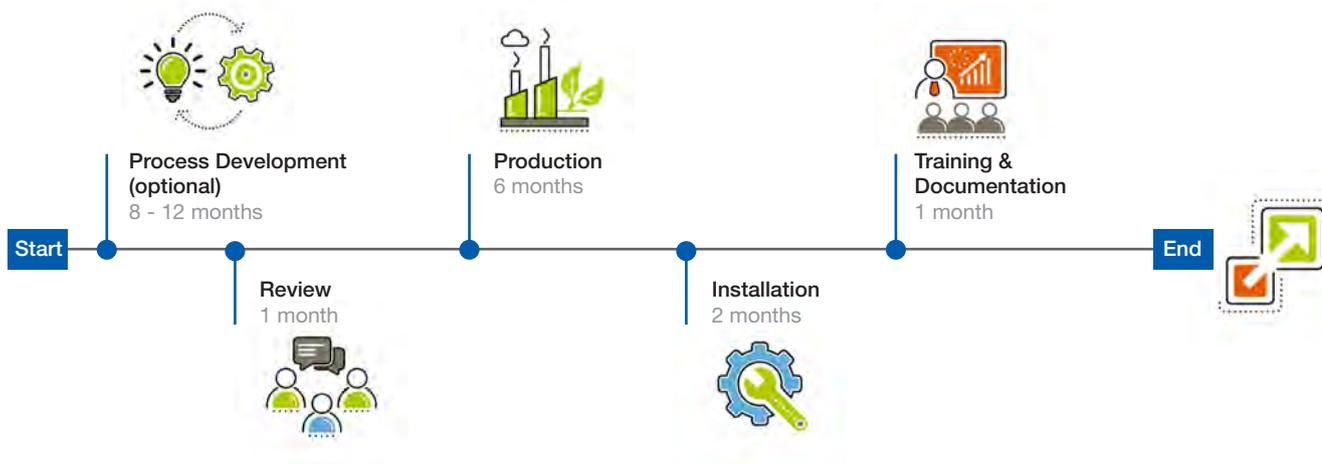
**Step 2 (Production):** With a purchase order in hand, both teams will order long lead time items to minimize production time. PODs are built entirely offsite and Pall starts bioprocess equipment production. After completion of the production an FAT will be executed to test the installations prior to delivery.

**Step 3 (Installation):** The G-CON team installs the PODs within days at the customer site and starts commissioning of the PODs up to IQ/OQ if desired by the client. The Pall team installs and commissions the entire bioprocess production equipment up to IQ/OQ if desired by the client.

**Step 4 (Training/Documentation):** G-CON provides training, an engineering turnover package, site acceptance test documentation, critical spare parts and/or spare parts list for the PODs. Pall provides equipment platform training for operators and service personnel, process validation, and consumables. Customized training can be requested upon needs.

**Figure 3**

A complete viral vector platform can be delivered, installed and validated in 10 months



## Further Information

For further information please contact Pall



**Corporate Headquarters**  
Port Washington, NY, USA  
+1.800.717.7255 toll free (USA)  
+1.516.484.5400 phone

**European Headquarters**  
Fribourg, Switzerland  
+41 (0)26 350 53 00 phone

**Asia-Pacific Headquarters**  
Singapore  
+65 6389 6500 phone

Visit us on the Web at [www.pall.com/biotech](http://www.pall.com/biotech)

Contact us at [www.pall.com/contact](http://www.pall.com/contact)

### International Offices

Pall Corporation has offices and plants throughout the world in: Argentina, Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, India, Indonesia, Ireland, Italy, Japan, Korea, Malaysia, New Zealand, Norway, Philippines, Poland, Russia, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan, Thailand, United Kingdom, and Vietnam. Distributors in all major industrial areas of the world. To locate the Pall office or distributor nearest you, visit [www.pall.com/contact](http://www.pall.com/contact).

The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

© 2020, Pall Corporation. Pall, , Allegro, Cadence, iCELLis, Kleenpak, Mustang, Stax, Supor, and Xpansion are trademarks of Pall Corporation. ® indicates a trademark registered in the USA. TM indicates a common law trademark. Filtration.Separation.Solution. and Accelerator are service marks of Pall Corporation.