PALL Biotech

USD 3318

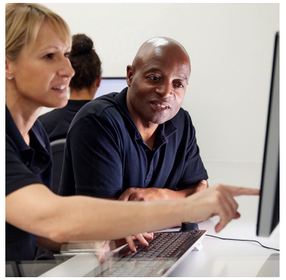
Integrated Solutions

Streamlining and simplifying gene therapy operations, helping speed you to market

*Filtration. Separation. Solution.*SM

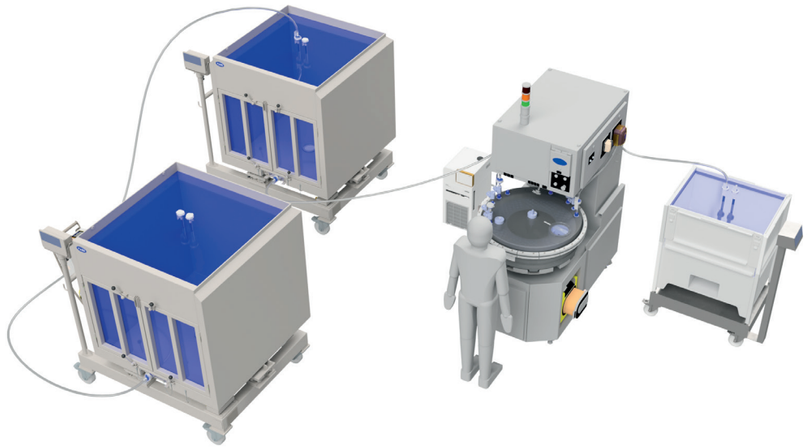
Integrated Solutions

An integrated solution utilizes engineering expertise to combine multiple unit operations into a single, centrally automated process, supported by comprehensive technical services.
This philosophy can be applied to two or more unit operations or be expanded to provide a complete end-to-end solution.



Benefits of Integrated Solutions

Moving to integrated solutions will help simplify and streamline your gene therapy manufacturing process, speeding time to market and reducing overall cost of goods. The simplified process, using standard equipment and qualified single-use system designs and components, lowers the risk for operator error which helps assure compliance with cGMP and assure product quality.



Pall Biotech Integrated Solutions

Our integrated solutions team combines best engineering and project management practices with an in-depth industry knowledge and diverse equipment portfolio to deliver these benefits on time and on budget, ready for when you need them.

Pall Biotech can provide fully integrated bioprocessing solutions for gene therapy, from discovery through to commercialization; from upstream through to final filling; from initial design through to implementation.

With a range of solutions covering multiple virus types, and with production in either adherent or suspension processes, our extensive single-use portfolio can offer you the complete solution you need.

Technical Expertise

Engineering and Scientific Expertise

Having the correct product offering is only part of the story – it is essential to partner with a provider who also has the engineering and scientific expertise and experience to deliver the optimal solution to meet your requirements.

We work with you to develop your system solution to meet your process requirements. Optimal system design is achieved based on our class leading know-how, considering physical and operational constraint mapping, whilst always keeping usability in mind. And with 4 biotech engineering centers of excellence, based in China, India, Germany and USA, the expert support you need is never too far away.

With a dedicated team of over 200 engineers based in 13 countries, speaking over 25 languages

Many of our engineers have come to Pall from biotech and biopharmaceutical companies, working on gene therapies, mAbs and other processes, so have a broad depth of experience from working in the industry.

Our team of over 270 scientists based in 6 hubs around the world, provide integrated global technical support from process development, validation and qualification, through to operator training, which enables you to rapidly transition from preclinical through to commercialization.

We can help you develop automation & control strategies including data integrity tests, PAT, data analysis and real-time release & digital batch records, ensuring you the benefit of robust security of supply for all process consumables and helping you meet stringent regulatory requirements.

Working with You

1

Discuss and Define

No two gene therapy manufacturing requirements are the same, so it is essential that we fully understand YOUR process and YOUR requirements before we propose any solutions.

Our process engineering know-how is best in class. We always approach each project by understanding YOUR process requirements down to a fundamental mass balance level and then tailor the best solution in terms of equipment selection and engineering design to meet those needs. Considering your virus type and your preference for adherent or suspension culture, you can be confident that, together, we will define the optimal solution.

In addition to matching technology and engineering with your process, we are also able to help you define your process. Our biotech PD services laboratories based in Portsmouth UK or Westborough USA can help you define an effective process to produce YOUR product.

2

Develop and Design

Based on your requirements and our expertise, we will design the equipment and consumables for your fully integrated solution, assuring connectivity between process steps, offering automation and control strategies, and ensuring regulatory compliance.

Our facility modelling software, with 3D visualization, ensures we design a solution around any physical or operational constraints, allowing you to evaluate various facility layouts to ensure your final design is optimized for efficiency, usability and flexibility.

3

Deliver

We will ensure your integrated solution is delivered within specifications, on time and within budget.

Our expert team of engineers and scientists will test (FAT/SAT/IV/OV) and help you validate (IQ/OQ/PQ) your integrated solution, and train operators to ensure you are fully cGMP compliant and operational as quickly as possible.

4

Support

Once your new process is up and running, we will continue to support you with ongoing training as required, regular servicing of equipment, and assurance of supply for all your process consumables.

Solutions for All Process Requirements

Pall Biotech's product portfolio is extensive and complete, allowing us to deliver integrated solutions for all the unit operations steps from upstream through downstream, to final formulation and filling, using batch, fed-batch or continuous processing. This ensures continuity and compatibility of materials and equipment, simplifying validation and qualification processes.

Designing Flexibility into Manufacturing

In today's market, manufacturers need to be able to quickly respond to changes in demand. Our range of single-use and hybrid solutions increases facility flexibility, to enable easy and fast modification of set-ups for different processes or to cope with increased capacity demands.

Proven Success

We have many years' experience in delivering integrated solutions to customers throughout the world, across the entire manufacturing process.

Upstream Downstream

Case Study 1

Upstream and Downstream Processing

Challenge:
Based in the USA, our customer wanted a complete single-use solution for gene-therapy viral vector contract manufacturing, which could be implemented in two existing facilities in the shortest possible time.

Solution:
The upstream solution included seed bioreactors, feeding into single-use stirred-tank bioreactors up to 1000 L for clinical manufacturing, and up to 2000 L for commercial manufacturing, with fixed-bed bioreactors for scale-up of adherent processes, and a variety of single-use mixers for media and buffer prep. The downstream purification solution included single-use tangential flow filtration systems, fluid automation systems, mixers, and single-use chromatography systems.

Added Value:
Our team delivered a cost effective end-to-end solution, within the required extremely tight time lines.

Upstream Downstream

Case Study 2

Upstream and Downstream Processing

Challenge:
A customer developing a high dose AAV gene therapy based on transient transfection of adherent cells required a full, scalable end-to-end manufacturing process.

Solution:
Pall designed a complete, integrated manufacturing solution starting with the Xpansion™ bioreactor as a seed train to the iCELLis® 500 bioreactor. A single-use downstream process consisting of clarification, purification and formulation was developed. The complete process was able to generate >1 x 10^{16} vg/batch.

Added Value:
Our technologies enabled the development of a full industrial process adapted from a small scale lab process, allowing the customer to move forward through clinical trials.

Upstream Downstream

Case Study 3

Upstream and Downstream Processing

Challenge:
A customer was looking to develop a gene-modified cell therapy and required >2 x 10^{12} IFU of 3 different adenoviruses each carrying a different gene of interest.

Solution:
Pall developed an end-to-end solution that was able to generate >1x10^{16} IFU using an iCELLis bioreactor on the upstream and then going through 4 downstream processing steps. The process was robust enough to work for all 3 different adenoviruses.

Added Value:
Our expertise with new technologies enabled us to make a full industrial process. In addition to increasing the scale of the process 158x, the process eliminated the need for 50 incubators and reduced the downstream processing time from 4 days to 1 day.

About Pall Biotech

With a global team supporting Pall Biotech, we provide the cutting edge products and services to meet your needs as you discover, develop and product life saving small and large molecule pharmaceuticals.

Our technology is backed by industry-leading, lifetime support solutions to assist you from upstream to downstream, and into final fill phases of drug production. And with 11 manufacturing sites around the world, you can be assured of continuity of supply.

Our multiple engineering and validation hubs sited in key locations mean you can work with our teams based in your region, to ensure projects run smoothly and efficiently.

And with over 70 years experience, you can be assured that we have the knowledge, expertise, and global infrastructure needed to deliver the solutions and service you require, to meet the challenges you face in this demanding, exciting, ever-changing market!

Process Development Services

Prior knowledge is a rare and valuable commodity, especially when preparing to take a new direction or when under pressure to deliver to a tight deadline. Take advantage of Pall's experience, process knowledge and technical know-how to help you achieve your goals.

From the optimization of an end-to-end continuous process to establishing the right parameters for a single unit operation, our teams of scientists are ready to work with you and to generate the data you need to make the critical decisions necessary for success.

Scientific and Laboratory Services

The scientific and regulatory knowledge that supports the selection, adoption and ongoing use of critical process technology, coupled with analytical, imaging and measurement capabilities, creates a versatile and practical resource ready to respond to an ever-changing industry. Pall duplicates these laboratories across the globe and leverages their cumulative knowledge to deliver practical scientific and regulatory support to all process technologies to keep you moving forward.

Technical Support

The accessibility of local technical support networks minimize delays in your journey at all points. From the early stage of process development to on-site support for mature processes, Pall's technical support groups are there to help remove barriers to progress and to make your journey as rapid and stress free as possible. Our knowledge of the technology and the process can be applied to everything from training to trouble-shooting and consultancy. Our global team of technology experts are on hand to respond to your changing needs.

Advanced Separation Systems

Operating within the defined design space demands the monitoring and control of critical process parameters to assure product quality. Systems that control critical unit operations and that communicate with your existing process components can control process risks and maximize productivity by reducing operator involvement for many processes, Pall applies strong engineering and regulatory understanding to deliver compliant and qualified systems that safeguard and simplify your journey.

Validation Services

Arriving at your destination counts for nothing without the necessary paperwork to proceed to the next stage. Pall's Validation Services are committed to delivering the supporting data packages and analysis required to quantify process risk and to support regulatory submission.

Our strengths include critical filtration technologies such as the performance validation of sterilizing grade filtration, and we are at the forefront of the evolving needs in the area of extractables and leachables for all product contact components. We combine the generation of data with interpretation and consultancy to deliver data packages that are ready for regulatory scrutiny and to ensure there are no barriers to progress.

PALL Biotech

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
Contact us at 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.

*Filtration. Separation. Solution.*SM

01/19, PDF, GN19.07275

USD 3318