



Biotech

USD 3333<sup>1</sup>

# Accelerator<sup>SM</sup> Process Development Services

Your biotech journey to industrialization starts here



The freedom to choose  
your biotech journey



*Filtration. Separation. Solution.<sup>SM</sup>*

# Industrializing Bioprocess Manufacturing

## Process development collaboration

The journey to commercializing a therapeutic is a complex and challenging one. It is filled with tasks that include ensuring patient safety, building a product portfolio, working with regulatory agencies, achieving economies of scale on a process typically designed at the academic level, defining a product platform, and addressing fluctuating demands – all while keeping down cost. With the ever-shrinking pool of resources and technical expertise, these can be daunting tasks to achieve. At Pall, we understand the issues you are facing, and while we may not be able to solve all of your journey's challenges, what we can do is help to minimize the risk. We deliver a robust, reproducible and scalable process that helps you move beyond laboratory scale process choices to those that are proven to support industrialized processes.

Using our global centers of excellence and our industry leading technology, we specialize in designing, optimizing and transferring scalable processes from pre-clinical to validated cGMP manufacturing. Choosing Pall as your process development partner will reduce your development time by leveraging our industry experts, proven methods and award-winning integrated bioprocess equipment. Once we design and optimize your process, you will receive specialized support and training from technical experts who will ensure the seamless and stress-free adoption of the platform at your designated manufacturing facility. This will minimize delays in your journey and increase your speed to market.

## Centers of Excellence



Take advantage of Pall's experience, global centers of excellence, process knowledge and technical know-how to help you achieve your goals.

- BL2-grade suites
- 900 m<sup>2</sup> of combined configurable lab space
- Latest innovations in Pall technology for large scale upstream processing (USP) and downstream processing (DSP)
- Cutting-edge laboratories specializing in continuous bioprocessing, and cell and gene therapy

# Technical Expertise

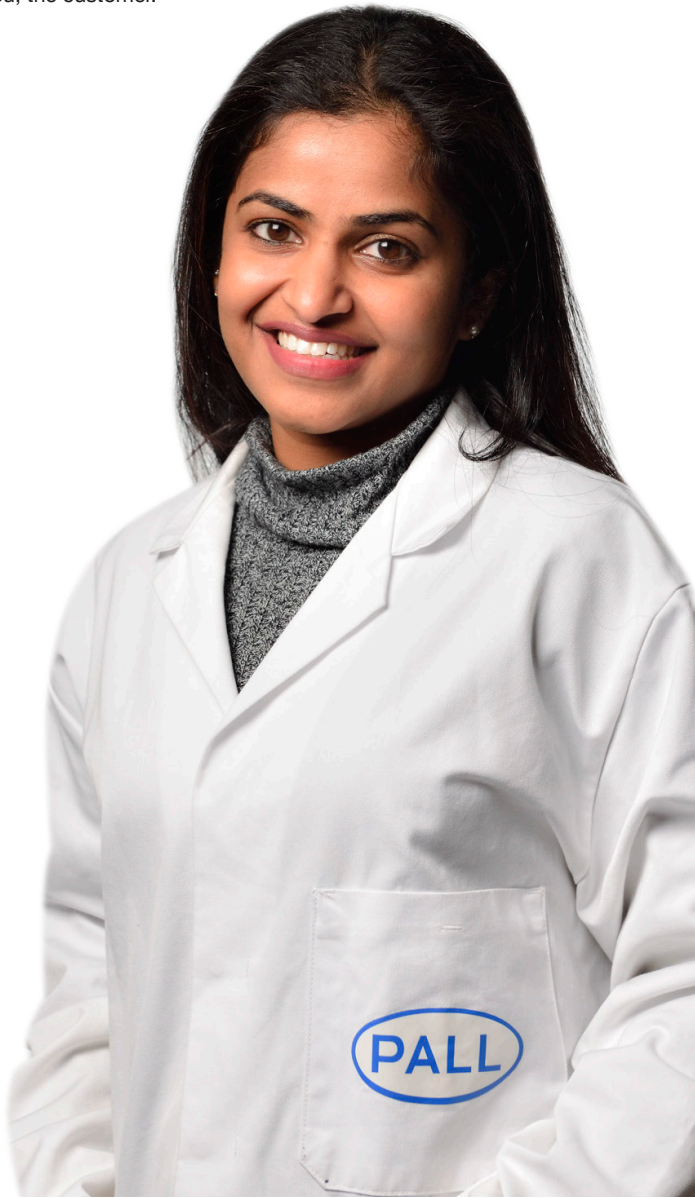
## Let's co-develop your journey

Our team of scientists and engineers know how critical your therapeutics' process development is and understand that you need a partner who not only delivers, but puts you, the customer, first.

Our promise is to co-develop an optimal platform solution by either simplifying your current process, or re-developing it from the ground up.

We believe that the most successful projects are centered around open and collaborative dialogue, and as such we emphasize co-development and approach each project with an open mind. We are ready to listen to your needs and ideas. We take the time to collect the background knowledge and to ensure that research objectives are aligned at every stage with your needs and expectations.

Working with Pall's Accelerator process development services means never paying royalties on any process that we develop together. We have a firm belief that each project belongs solely to you, the customer.



But don't take our word for it. Instead, listen to what some of our customers have to say about working with Pall's process development team.

“ .....

I was struck by the pragmatic approach in the process development work that Pall Biotech did for us. Science based and well-structured experimentation kept the project in a continuous flow and time to completion was impressive. The team at Pall were proactive and transparent and kept a high level of communication. The outcome was a continuous purification process that fulfilled our productivity and purity goals.

Maarten Pennings, CTO, BiosanaPharma

.....”

# Working With You

Moving you out of the laboratory into an integrated end-to-end manufacturing solution



No two manufacturing requirements are the same, so it is essential that we fully understand your process 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 process development laboratories can help you define an effective process to produce your product.

## What We Do

We can help you develop and plan the best production process for your requirements

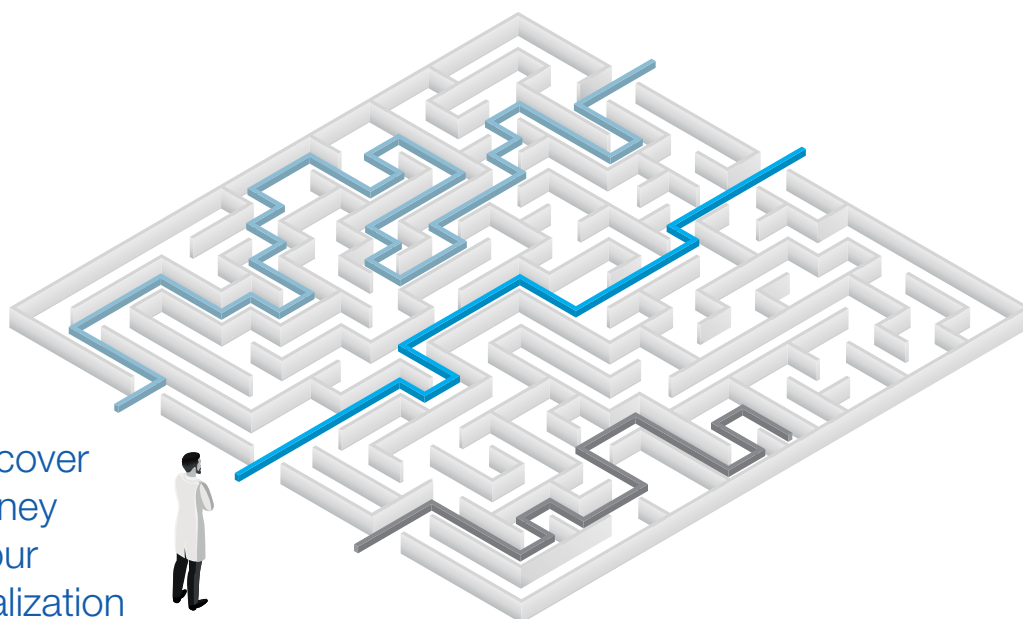
Prior knowledge is a rare and valuable commodity, especially when preparing to take a new direction or when under pressure to deliver to a tight deadline. Our team has extensive technical upstream and downstream expertise working with gene and oncolytic therapies, monoclonal antibodies, cell therapy and vaccines, to name a few.

We develop a fully integrated end-to-end platform, carefully optimized from the seed train strategy through to minimizing the number of operations for scale-up.

Our goal is to design a process with the end in mind, ensuring that it's tailored for manufacturing environment, focusing on simplicity to reduce risk.

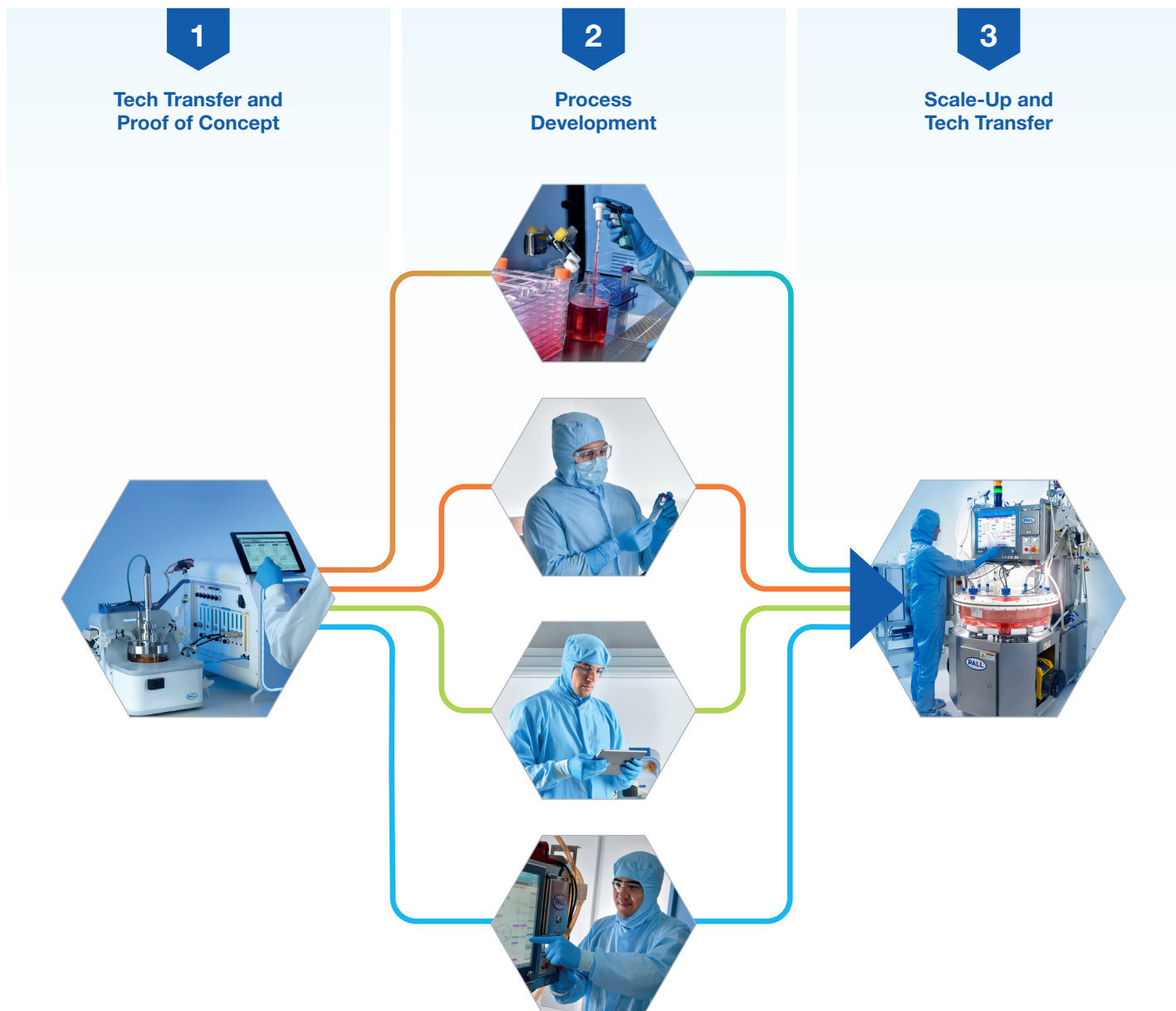
We will deliver a platform that is not only designed to scale as you progress through the drug development cycle, but one that is versatile and gives you the flexibility to adopt additional therapeutics in your pipeline if required.

Helping you discover a simplified journey to accelerate your path to industrialization





# How We Do It



## Tech Transfer and Proof of Concept

- Review and replicate the current manufacturing process
- Define the end goal
- Proof of concept
- Cost modeling and return on investment (ROI)

## Process Development

- Optimized process (USP & DSP)
- Improve process productivity
- Prove reproducibility

## Scale-Up and Tech Transfer

- Scale-up process
- Process and knowledge transfer
- Deploy trained operators for onsite support and training

# Let Us Take Your Process To The Next Step

Choosing Pall's Accelerator process development services will alleviate your pain points when it comes to scaling your project to clinical manufacturing

Through our hands-on approach, our team of experts will develop a versatile technology platform that will help you accelerate your speed to market as well as develop your clinical stage strategy.

Additionally, you can rest assured that your platform is designed so that it can be deployed with multiple drug candidates, saving you both time and money.



## Why Stop There?

We have formed several strategic partnerships that give you the option to tech transfer your process into a pre-fabricated modular facility that not only defers your initial capital investment but gives you the flexibility to address fluctuating demands of your drug.

## Accelerator Process Development Services



### Robust, Scalable Process

We work closely with you to develop a fully integrated, end-to-end platform that can be applied to multiple drug candidates and uses technology that is ready for all scales of manufacturing.



### Trust and Collaboration

We co-develop your platform with a collaborative dialogue to build and maintain trust. We will ensure that your process is designed to meet your requirements and to be versatile enough to be applied to additional therapeutics in your pipeline as required.



### Technical Experts

Our global team has extensive upstream and downstream expertise across a wide variety of processes including gene therapy, cell therapy, immunotherapies and vaccines. We are here to help when you are under pressure to deliver to a tight deadline or when you are preparing to take a new direction.

## 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.

### 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.

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!

### 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.



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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)

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#### 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).

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