Providing Comprehensive OEM Solutions

Membranes and Devices For Life Sciences Applications

Drug Delivery • Liquid & Gas Filtration • Diagnostics • Laboratory • BioPharm
As the world leader in the design and production of membranes, filtration devices, and separation systems, Pall supplies products to nearly every industry in the world. For over 50 years, our customers have relied on Pall for their most sophisticated applications in drug discovery, healthcare, biopharmaceuticals, municipal water, aerospace, hydraulics, industrial fluid processing, and more.

With Pall you gain access to a global, multi-site manufacturing organization with an impressive portfolio of products, quality systems, and experience to meet the diverse requirements of your internal and external customers.

You need more than a tangible product...

You need a reliable business partner with a proven track record in technology innovation, manufacturing excellence and regulatory compliance. At Pall, we know you’re counting on our ability to supply products that meet the quality and performance standards your customers demand and to work within your budget and timetable. Our OEM business approach is founded on four core competencies.

1. **Membrane Manufacturing** – Pall offers the broadest selection of membrane chemistries ensuring optimal performance for your purpose.

2. **Device Engineering** – By combining the right membrane with the right device platform, you get the best combination for your filtration, separation, purification, or detection application.

3. **Scientific and Laboratory Services** – Pall’s expert testing and scientific support is available from more than 20 dedicated locations across the globe.

4. **Manufacturing/Quality/Logistics** – Our global manufacturing network and experience in regulatory compliance and supply chain optimization enhance the reliability of our customer’s operations.

As you review the following pages you will discover how Pall’s unique service capabilities and commitment to quality deliver more value than any other supplier in the industry.

Connect with our collaborative spirit and together we will improve the quality of life for us all.
Pall offers a wide selection of filtration, separation and purification materials to help you optimize your product performance and minimize your development project costs. Whether you are choosing from our standard product portfolio, requesting a modification on an existing product or exploring the development of a completely new formulation, Pall will deliver precisely what you need. If the perfect material does not exist yet, we’ll develop it for you.

Our extensive portfolio of OEM materials offers you flexibility and peace of mind, knowing that you will find the right solution for your application needs, including:

**Microporous membranes**
- Acrylic co-polymer
- Cellulose acetate
- Nitrocellulose
- Nylon
- Polyethersulfone (PES)
- Polypropylene
- Polysulfone
- Polytetrafluoroethylene (PTFE)
- Polyvinylidene fluoride (PVDF)

**Asymmetric membranes**
- Polyethersulfone (PES)
- Polysulfone
- PVDF

**Ultrafiltration membranes**
- Polysulfone
- Regenerated cellulose

**Porous ceramics substrates**

**Fibrous materials**
- Composites
- Glass fiber
- Metal
- Polyester
- Polypropylene

**Non-woven materials**
- Polyester
- Polypropylene

You can choose Pall membranes with confidence. Our time-tested quality systems are designed to ensure the production of media with exceptional lot-to-lot consistency and reproducibility.

**Advantages of Pall membranes and separation materials**
- Largest selection of microporous materials
- Wide range of material performance and surface chemistry characteristics
- Compatibility with multiple sealing technologies and sterilization methods
- Extensively used in manufacturing of FDA-regulated devices
- Manufactured to exacting specifications and under strict quality standards

Consider us your partner in planning, developing, and delivering solutions.
Founded in an impressive record of accomplishments in membrane development and manufacturing, the design and production of membrane-based devices are the ultimate expression of Pall’s engineering and technology capabilities. This is where it all comes together—high performing membranes, flexible housing configurations and devices designed to deliver efficient, safe and reliable performance.

At Pall, active listening and thoughtful consideration of your project goals and requirements are the starting point in the product development process. Working in close collaboration with you, our R&D scientists and engineers bring their multidisciplinary knowledge and years of experience into creating the best product for your specific application. From the presentation of a comprehensive proposal, to proof of concept and prototyping, to validation and manufacturing, we stay in close communication with you to ensure that the project is completed on time and on budget.

If your application requires one of our existing products to be modified, our Rapid Response team of engineers is ready to help. Their expertise in integrating filter media, housing design and connector configurations allows them to optimize our product to your application quickly and effectively. Working with Pall can reduce engineering, mold and equipment costs, as well as speed up your product’s time to market.

**Device platforms**
- Blood filters
- In-line liquid and gas filters
- Large-volume process filters
- Multi-well filter bottom plates
- Non-vented epidural anesthesia filters
- Pleated filter elements
- Smoke and odor removal filters
- Syringe filters
- Vacuum line filters
- Vented IV filters (adult, micro, and pediatric)

**Depend on Pall to keep your project on target and on budget.**
Pall’s Scientific and Laboratory Services (SLS) is a cornerstone of our service commitment. This world-class SLS Department consists of over 400 Ph.D. scientists, engineers, and technicians ready to help you. Pall’s SLS personnel operate from more than 20 well-equipped laboratories in North and South America, Europe and Asia. We’re here to help you anticipate, identify, and solve any challenges your applications present.

Our worldwide SLS staff has expertise in the life sciences, microbiology, physics, engineering, and related scientific disciplines as well as years of field experience in fluid clarification and membrane-related separations processes. SLS will help you achieve the best economics and performance from your Pall membranes and meet all relevant government requirements.

Pall’s SLS facilities in Portsmouth, England; Port Washington, New York; and Tsukuba, Japan are ISO9001 certified. Regional SLS laboratories are strategically positioned to provide rapid response to our customers’ technical needs anywhere in the world, at any hour.

**Scientific expertise always ready to support your application needs.**

**Solving and supporting**

Our SLS laboratories employ advanced equipment and sophisticated analytical methods to evaluate all aspects of your process and application. The multi-disciplinary technical and scientific staff brings a world of experience to help you succeed. Laboratory capabilities include:

- Biochemical diagnostic testing
- Chemical compatibility testing
- Contamination analysis
- DNA and protein detection
- Drug binding studies
- Emission and absorption spectrophotometry
- Gas and liquid chromatography
- Hematology
- Light and electron microscopy
- Microbial and endotoxin challenge testing
- Particle counting

**Benefit from Pall’s technical and scientific resources.**
Acceptable just isn’t good enough. You need the best OEM solution available.

Manufacturing Excellence
Pall’s microporous materials and filtration devices are manufactured under precise, highly controlled conditions. Our global manufacturing operations employ Lean Manufacturing and Six-Sigma principles, and internationally recognized quality systems, to produce products of exceptional quality and value. Pall’s OEM device manufacturing facilities utilize the most advanced sealing technologies, vision systems and robotics platforms to ensure optimum operational flexibility, fast response times and lot-to-lot consistency.

Supply-Chain Initiatives
Our commitment to total customer satisfaction does not end with an on-time delivery of a quality product. We partner with our customers to implement continuous supply programs designed to reduce inventory costs and increase the efficiency of the supply chain. Pall’s consignment inventory and Kanban programs together with our global manufacturing and service networks are value-added resources that can significantly reduce your total cost of ownership.

Pall is committed to continual improvement to meet the unique quality demands of customers worldwide.

- For the past 10 years, Pall has received praise for producing the cleanest and most reliable IV filters on the Japanese market.
- Five years ago, Pall Ann Arbor initiated an internal Kanban program with our suppliers. It was so successful at reducing our inventory costs that we went on to launch successful Kanban programs for many of our clients. Kanban and consignment inventory programs can reduce your carrying costs while minimizing lot inventory sizes. Our ability to electronically interface with you keeps you at the forefront of supply chain management.

The end result? A strategic competitive advantage for your company.

Regulatory Compliance
All Pall Life Sciences facilities maintain certification to the ISO9001 Quality Management System (QMS) Standard. The medical device manufacturing facilities are FDA registered establishments qualified to manufacture and distribute medical devices and comply with FDA Quality System Regulation, 21 CFR Part 820. Additionally, these facilities maintain QMS certification to ISO 13485 and the Canadian Medical Device Conformity Assessment System (CMDCAS) and have the authorization to CE Mark finished medical devices as appropriate.
Ease of use – one mark of quality

Pall takes pride in designing advanced technology products that are also easy to use.

When one of our customers started using Pall’s Adult IV Filter for their filtered delivery sets, they requested assistance. Their old filter was complicated, requiring manipulation to prime. The Pall filter, on the other hand, was elegantly simple. End users in the medical community could hardly believe that such a powerful device could be so intuitive.

Pall worked with the customer at all levels of their organization to demonstrate the filter’s performance and effectiveness. We went beyond training, however, and accompanied our customer to their end user to identify and address their concerns. This multi-level collaboration resulted in satisfied, confident end-users and a strengthened customer-Pall relationship.

Optimizing inputs – engineering outside the box

Making good products better—and better products superior—is at the heart of Pall’s technology mission. A customer’s blood collection application had been successfully relying on one of Pall’s high-performing membranes for years. But it was time for an upgrade.

In an effort to optimize the application’s performance, we embarked on a Six Sigma project to evaluate how we manufactured the membrane. Pall scientists tested numerous process inputs that are not used in connection with the product specification or release criteria. We suspected that these overlooked inputs held the key to optimizing performance.

This creative approach led Pall to discover an input parameter that improved performance dramatically. We adjusted the process accordingly and developed a test to measure its impact. The difference was substantial, and our customer’s blood collection application saw an immediate benefit. Pall’s innovations in manufacturing and evaluation methods enhance the quality of all its membranes.
Drug Delivery and Biotherapeutics

Offering exceptional consistency, our product line has been engineered to meet the critical requirements for specific medical applications, including drug delivery, general surgery, renal care, and biotherapeutics.

Pall’s OEM membranes and devices have been used for decades by leading drug manufacturers to ensure the safe and effective administration of intravenous drug preparations. Our in-line intravenous filters reduce the risk of contamination and the potential for costly secondary infections that may occur during infusion therapy. Pall’s IV filters effectively eliminate air introduced during priming or set-up of IV lines, helping to prevent potentially fatal air embolisms. These time-tested products are also effective in removing inadvertent manufacturing by-products or contaminants such as glass or plastic fragments, drug precipitates or aggregates. If not removed, these contaminants may increase the incidence of undesirable adverse reactions and immune responses in patients.

Pall membranes exhibit performance characteristics that hold exciting potential in the growing field of cellular and molecular-based therapeutics. As the benefits of therapeutics are further explored, Pall will continue to research ways to use Pall membranes to capture, collect, separate, and prepare cells using these new technologies.

Applications

Infusion therapy
- Antibiotic therapy
- Apheresis solutions
- Aqueous IV solutions
- Delivery of epidural anesthetic and analgesic solutions
- Lipid/TPN infusion
- Neonate and pediatric IV therapy

Non-invasive therapy
- Blood separation
- Respiratory therapy
- Transdermal drug delivery
- Wound care

Pharmacy admixture
- Extemporaneous morphine, radiopharmaceutical, allergens extracts or ophthalmic solutions
- Injections (glass ampoule drug injections, epidural or intraocular injectables)
- Nutrient or pharmaceutical admixtures
- Preparation of chemotherapeutic agents
- Preparation of irrigation and injectable solutions

General filtration and prefiltration
- Large-volume fluid sterilization
- Personal hygiene and care of immuno-compromised patients
- Preparation of food and beverages for high-risk patients
- Surgical hand washing
Patient, Personnel and Equipment Protection from Medical Gases

Pall gas filters offer optimal levels of bacterial and viral protection. Our unique filter designs provide an effective barrier for reducing cross-contamination between patients, medical equipment, and the environment. Extensive testing guarantees their top performance and reliability in even the most demanding applications.

Applications

- Contamination control
- General gas filtration
- Instrument protection (transducers, gas analyzers)
- Insufflation
- Odor removal
- Oxygen concentration
- Pump and vacuum line protection
- Respiratory therapy (adult and pediatric)
- Smoke evacuation/elimination
- Sterile gas and air delivery
- Ventilation (IV vents, suction canisters, urine bags, packaging, spike vents, ostomy bags, enteral feeding packaging)

OEM Components for Medical Administration Sets

Pall offers a variety of high-quality OEM components for medical administration sets, including IV, blood, neonatal, and apheresis applications. This allows our medical partners worldwide to consolidate purchasing through one vendor while maintaining confidence in product quality. Pall OEM medical components are produced and assembled under quality management systems that are certified to meet ISO 9001 and ISO13485.

Component Types

- Blood bag components
- Blood bags
- Blood pump
- Check valves
- Drip chambers
- Filters
- Luer connectors
- Spike entry ports
- Tubing
- Tubing clamps
- Tubing connectors
Proactive product development – clog-free filters

Safety needs don’t wait, and neither does the market. When the medical community took measures to protect vacuum pumps from biohazardous waste, Pall took this effort to the next level.

Hospital personnel were using the filters they had available which lost suction, created back pressure and clogged too often. In addition to creating frustration, these problems created new risk. Pall saw these problems as an opportunity. We knew we could produce a better vacuum pump filter.

After a rigorous analysis, Pall designed a filter that optimizes pump and flow performance. Exceptional protection properties and clean, smooth action resulted in Pall Vacuum Filters being adopted worldwide.

Product development at the pace of business

Short-term solutions proved to be part of the problem. Ongoing quality issues with a customer’s blood bag supplier had adversely affected delivery. The supplier’s rush to improve delivery, in turn, had caused product quality to deteriorate further.

By the time Pall was brought in to solve these large-scale quality and delivery issues, our customer’s business was in jeopardy. They needed a blood bag they could trust, and they needed it immediately.

Pall put together a comprehensive, international task force to create the right product on a demanding schedule. The collaborative team of Pall manufacturing, marketing and sales, R&D, quality, and our customer took less than six months to accomplish its mission. The customer’s specified blood bag product had been developed from start to finish, including design, packaging and labeling changes, validation, and filing with the FDA. With the root problem solved, the customer’s business was back on track.

Pall can provide long-term solutions on short notice.
Identifying risk factors before disease develops

Coronary Heart Disease (CHD) is the single highest cause of premature death in the Western world for both men and women. One of the major contributing factors to the disease is high cholesterol.

In 2004, a University spin-off company unveiled a diagnostic multi-analyte detection system that uses Pall’s Asymmetric Blood Separation Membrane. The assay system, based on electrochemical strip technology, measures several analytes simultaneously and provides quick and accurate results on an easy-to-read digital handset. After two years of trials and close collaboration, the test has finally been optimized using Pall’s Plasma Separation Membrane and Hydrophobic Vent Media.

The first of several multi-parameter tests to be launched is a cardiac risk test, which provides simultaneous results for total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides. With early risk detection, the first test promises countless people longer and healthier lives.

Advanced diagnostics – making technicians more effective

Now more than ever, technicians are called upon to perform diagnostic procedures in non-clinical settings. This means point-of-care diagnostics need maximum portability with minimal room for error. The increasing complexity of the procedures themselves compounds the challenge.

Pall was asked to develop a blood cell separation device that technicians could use easily and reliably at the point of blood collection. A one-step, closed system was required—but one that would be sophisticated enough to collect high numbers of white blood cells from whole blood while removing over 98% of red blood cells.

To answer this need, Pall R&D, scientists, engineers, and sales people teamed up with the customer to design a filter format that is user-friendly, cost-effective, and superior in performance to other products on the market. Together, we attained our goal. Today, technicians’ kits carry Pall’s blood cell separation devices for the collection, stabilization, and transport of high quality nucleic acids from whole blood.
**Molecular Diagnostics and Molecular Biology**

From sample preparation to DNA/RNA detection, Pall membranes and devices provide endless possibilities for molecular applications. Pall’s membranes for transfer, immobilization and detection set industry standards for reproducible results, durability and high signal-to-noise ratios. These membranes can be used for nucleic acid and protein purification applications and are compatible with radioactive and non-radioactive detection systems. For sample clean-up or concentration, Pall offers membranes for microfiltration and ultrafiltration that can be integrated into a variety of existing device platforms including multi-well plates, slides, plastic films, centrifugal devices, and syringe filters.

**Applications**

- Bead assays
- Biomolecule isolation and detection
- Colony and plaque lifts
- DNA fingerprinting
- ELISA/EIA solid-phase immunoassays
- Gene probe assays
- Immunochromatographic assays
- Macroarrays
- Microarrays
- Nucleic acid dot/slot blots
- Oligo synthesis
- Prefiltration
- Protein blots/slot blots
- Protein sequencing
- Sample preparation
- Southern (DNA) Northern (RNA), and Western (protein) transfers

**Traditional Diagnostics**

For the speed and sensitivity your customers demand, choose from Pall’s versatile selection of microporous and fibrous materials. From sample, conjugate and absorbent pads to membranes with distinct surface characteristics and defined binding characteristics, Pall offers a wide variety of materials especially designed for in-vitro test applications.

**Applications**

- Biosensor utility
- Blood separation
- Dipstick tests
- Dry chemistry test strips
- Finger stick assays
- Flow-through assays
- Gene probe assays
- Glucose assays
- Immersion assays
- Lateral flow assays
- Reflectance-based assays

[Image of laboratory equipment]
General Laboratory Filtration, Separation, Detection and Analysis

Pall’s expertise in lab applications extends past the life sciences into a variety of analytical, microbiological, and environmental procedures. Our membranes and membrane-based products define methods and set performance standards worldwide. Pall can help you design products optimized for laboratory cleanup, preparation and detection procedures that will meet stringent government and industry guidelines. When the goal is protecting public safety or industrial economics, you can count on Pall.

Applications

- Analytical sample preparation
- Biopurification and laboratory separations
- Combinatorial chemistry and high throughput screening
- Diagnostics
- Drug delivery
- Environmental testing and analysis (water, air, and hazardous waste)
- Liquid sterile filtration in buffers, media and complex fluids
- Microbiology QA/QC
- Venting and gas filtration

Ensuring Product Safety

A biopharmaceutical blow/fill/seal packaging equipment manufacturer required both venting and liquid filtration on their equipment. It is critical these machines package sterile product. Pall provides 0.2 µm filters for both gas and liquid on these systems along with modified filter housings that fit the manufacturer’s design. The customer required that these filters were integrity tested as part of their system. The Pall FlowStar equipment is now incorporated on most machines sold to perform automated integrity testing.

Biopharmaceutical Processing

We offer the abundance of our Life Science Biopharm product portfolio to improve our customers’ processes. Whether you require a porous metal filter to prevent particulate from clogging vital autoclave parts, a 0.2 µm cartridge filter to filter flush water on an endoscope cleaning machine, or a Kleenpak® connector to aid in developing aseptic systems, Pall offers state-of-the-art biopharmaceutical solutions.

Applications

- Aseptic filling machines
- Blow/fill/seal machines
- Biosafety lab development
- Customized fermentation skid designs
- Cytometers
- Endoscope machines
- Filter dryer systems
- Steam systems
Customized solutions for laboratory applications

When a large multinational healthcare company faced the need to comply with new European regulatory requirements, they discovered that the method and materials used in performing the test would have to be drastically changed. The new testing procedure required the monitoring of high purity water samples at 80 °C. The microbial monitoring products used at that time were not compatible with such high temperatures and the method employed several testing materials and exposed the sample to secondary contamination risks.

Working in close collaboration with the customer, Pall product development engineers were able to identify the appropriate filtration material and designed an innovative microbial sampling device. The new device was not only capable of withstanding the high temperature but also provided an integrated solution that simplified the sampling and testing process improving efficiency and reducing overall costs. The final product provided a closed and integrated system that the customer can use for collection, transporting and filtration of 80 °C samples for microbial monitoring.
Pall offers the largest selection of membranes for life sciences and medical applications, and industry leading research, development, and manufacturing resources. Look to Pall for your OEM and custom product design, and you’ll find a partner uniquely positioned to put your needs first. Define your project and let us put our vast resources to work for you.

Detailed product data, specifications, technical reports, and protocols can be found at: www.pall.com/oem.

“I depend on Pall.”

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