Automated Separation and Purification Systems

MEETING THE NEEDS OF THE PHARMACEUTICAL INDUSTRY
Global Expertise
Global Expertise

Pall Corporation is the most widely qualified supplier of separation and purification solutions. Our total sales turnover is more than US$ 1.5 billion.

Pall’s unique capability comes from a strong blend of biopharmaceutical expertise, leading technologies and customer support. We provide reliable and fully integrated solutions for design, manufacture, sales and servicing of our products. Comprehensive support is available in all parts of the world.

Experience

Pall Life Sciences handles all purification and separation applications from bulk preparation and synthesis to biological and biotech-based production of active ingredients, to downstream processing and formulation and final filling of products. More than 50 years experience in providing proven engineered solutions is a good basis to partner with us.

Time

Timely process development and the procurement of production capacity are crucial for our customers’ success. We know development of new drug products is a demanding and costly exercise. Pall has expert teams available at every stage of the process for fast and flexible solutions.

Quality

Drug products have to be available at a consistently high quality with manufacturing and equipment subject to comprehensive validation and documentation. Pall® systems, already present in more than 1000 customer applications, fulfil exacting demands in design and manufacture, resulting in excellent process reproducibility and reliability.
Process Engineered Systems

In the biopharmaceutical and biotech industries, a detailed knowledge of the user requirements and operation to cGMP is a must. We design and build high quality process systems that are customized to each specific need. But we also start each project from a very long experience of proven know-how to ensure cost effective solutions and timely delivery.

Technology

Pall has more in-depth knowledge of matching the technology to the application than any other system provider. That’s because we also develop membranes and manufacture a wide range of filtration and separation modules used in many of our systems. And we continuously research and innovate to bring new solutions for improved separations.

The GAMP Approach

Development of automated solutions in the pharmaceutical industry is of growing importance to keep pace with commercial pressures and regulatory requirements. We fully recognize this in our project organization and documentation at every stage, from planning through to operation. We offer all levels of automation and we regularly participate in industrial and regulatory meetings and steering groups to keep ourselves and our customers up-to-date with requirements.

Customer Support

Correct advice before the order, dedicated project management and continued service thereafter is a key to success. Pall’s project management teams are located in all major countries and we have in-house manufacturing, assembly and test facilities for systems in three continents and more than five countries. This means that wherever you choose to locate, we will provide experienced support.
Process Engineered Systems

- Enquiry or Tender
- Process Development
  - Early Process & Engineering Design Technical Review
  - Initial System Design & Accurate Budget Cost Submittal
  - In Depth System & Process Design Review
  - Final System Design & Fixed Price Submittal
  - Contract Review Meeting
  - Regular Project Review & Update Meetings, Reports
  - System FAT (Factory Acceptance Test)
  - Delivery & SAT (Site Acceptance Test)
  - Ongoing Support
The requirements for a new process are seldom the same. Therefore, we begin each enquiry with a project review based on the individual requirements.

Our product portfolio and technology platform is comprehensive and allows us to always offer the best technical approach for each application. We use proven features, proven designs and proven packages wherever appropriate.

**Short Timescales - Best Results**

The time-span from drug development to market introduction is crucial for commercial success. With our extensive experience and production capabilities, Pall can help to keep this time to a minimum. Our project teams focus on your requirements and directly interlink with your team over the whole project from specification to commissioning. This approach helps to build each system to your user requirement specification, with the right validation documentation in the shortest possible time.

**Process Automation for Cost Savings**

With GMP and documentation requirements increasing, process automation is a good investment to optimize overall production costs: Less operator interference makes processes run smoothly, validation easier and with minimum downtime.

Pall’s automation solutions are designed for process integration and interfacing, in compliance with 21 CFR 11, from simple data logging to full batch records with electronic signatures.

**Expert Application Knowledge for Our Customers**

Pall has a large multi-disciplinary team of engineers and scientists with in-depth knowledge of applications and operating parameters for separation systems in biological, biopharmaceutical and chemical processes. Operating within the PASS (Pall Advanced Separations Systems) group for projects and within the SLS (Scientific and Laboratory Services) and R&D organizations for longer term development and analysis, they enhance the total package for process development and advanced solutions.
Pall’s large technology platform consists of both established and innovative modular components. This, together with our extensive applications engineering know-how, is a key to your success.

- Totally integrated process solutions
- Highly reproducible processes
- Low production costs through advanced technology
- Competitive advantage in yield and quality
- Flexibility in scale and modular increments
- Highest standards for cleanliness
- Integration of disposable and cleanable options
- Environmentally sound systems
- Comprehensive product and process documentation packages
The **PallSep VMF** technology is technically unique and is differentiated from other tangential flow filtration (TFF) systems in that the membrane stacks are oscillating, enabling the feed retentate recirculation to be reduced to a minimum. This not only saves energy, but also allows for higher transmission of target molecules, reducing diafiltration volumes and increasing overall product yields. The systems are often used in certain cell clarification or high solids situations where conventional TFF may not be optimal.
**TFF Cassettes**

Typically used for tangential flow ultrafiltration (UF) and microfiltration (MF) this technology offers very efficient performance with small space requirements. The compact units also minimize total system volume, which in turn allows for high final concentrations and reduced flushing and cleaning fluid volumes. Pall produces a wide range of scaleable products with high performance membranes in application-specific formats and specific molecular weight/pore size cut-offs.

**Hollow Fiber Modules**

For certain applications ranging from perfusion (cell recycle) to high purity water, hollow fibers from a choice of membrane materials, inner diameters and cut-offs have shown to be advantageous. Microza hollow fiber modules are remarkably robust and various options allow for steam in place and back-flushing during operation to prolong running times between cleaning cycles.

**Ceramic Technology**

The highest chemical and temperature tolerance in crossflow applications is provided by Pall’s Membralox range of ceramic membranes and modules. With many years experience of continuously developing and using these products, generally recognized to be the leading brand, we are well positioned to allow customers their optimum choice according to the application. A combination of innovative product features and systems design knowledge means unique performance benefits for many Pall customers selecting this option.
**Cartridge Filters**

Automated and manual skids save labor and time in many filter cartridge applications. Pall’s large range of direct flow filters (DFF) for clarification, prefiltration, sterilizing filtration and virus clearance are combined effectively with process control for optimized designs. Palltronic® instrumentation and logic is integrated into these systems where integrity testing is needed. Maximum use of disposable components is also employed in cases such as multi-purpose processing where high changeout rates are desirable.

**Sheet Depth Filters**

For solid liquid separation in many parts of the biopharmaceutical and blood fractionation industries, the highest productivity and efficiency is offered by Pall’s range of sheet filters. The superior enclosed design of the MEMBRapan® DGM sheet filter press plays a safe and effective role in these processes and allows full integration in automated processes including clean-in-place (CIP) and steam-in-place.
Chromatography

Pall’s chromatography systems achieve consistent scale up and accuracy with the highest standards of cleanliness and system hold up volume.

Euroflow ‘Resolute’™ columns achieve optimal efficiency, capacity and peak symmetry with very low pressure drop and true linear scale up to at least 2m diameter.

Packing support service and know-how across a full range of media are valuable elements in the total package. This is complemented by a range of packing system control systems, including the unique capability to monitor and control packing with a patented and validated ultrasound method. Integration of disposable Mustang membrane chromatography for polishing steps can further improve competitive advantage.

Other Technologies

Pall’s total portfolio of technologies for biopharmaceuticals ranges from separation by coalescing to particle or carbon removal by centrifugal depth filters (ZHF) and disc tube devices for high pressure RO. We also supply highly effective systems for production and distribution of pharmaceutical grade water. Please contact your Pall representative for advice regarding application of these or any of the other sections above.

Above and Left: Chromatography Columns and Systems
GMP and GAMP Approach

Planning

- Process Requirement
- Equipment URS
- GxP and Safety Review

Control System URS

- Control System FS
- Operating Interface Design
- Control System Design

- Design Review and Approval

Mechanical and Electrical Design

- Equipment FS

Verifies

GMP and GAMP Approach

- Equipment FS Control System URS
- GxP and Safety Review

- Operating Interface Build
- Control System Programming

- FAT & SAT
- Module Integration and Development Testing

- Installation Check
- Operational Check

- Installation Qualification

- Operational Qualification

- Performance Qualification

- Operation & Maintenance

- Retirement
The GMP requirements on validation for automated systems in biopharmaceutical production are defined in Annex 15 of the EC Guide to Good Manufacturing Practice of Drug Products and in other international regulatory guidelines. For the US market, 21 Code of Federal Regulations Part 11 further influences the design of electronic recording systems. In addition, the ISPE Forum has published its comprehensive GAMP Guide to create a common project design approach for industry users and vendors, from a formal user requirement specification to system commissioning and ongoing maintenance of a validated system. The ASME Bioprocessing and European (EHEDG) guidelines are also important reference points for specific equipment.

Over and above these general guidelines, Pall brings its long-standing experience in design and manufacture of purification and separation systems for GMP applications. This unique combination of experience in implementation of sanitary design and regulatory requirements together with process technology know-how provides reassurance of our ability to meet quality targets.

During the whole qualification phase of a new project, Pall is ready and willing to provide support services. We routinely provide a clear understanding of the scope of responsibilities, develop formal validation plans and are prepared to assist with all stages of qualification from factory acceptance through to site installation.

When in operation, your Pall system can be monitored continuously to predefined parameters and all relevant process data logged in a comprehensive batch record file to assure the consistency of your process in accordance with cGMP criteria.
Customer Support
Customer Support

Pall is organized functionally and geographically to give us the closest link to our customers and fastest response times.

Pall Advanced Separations Systems

Pall Advanced Separations Systems (PASS) is the applications, engineering and procurement entity for Pall’s global process systems business. To successfully deliver integrated solutions that meet industry and customer requirements this group has excellence in:

• Process system design
• Project management
• Systems fabrication
• Documentation
• Risk analysis
• Validation/qualification
• Installation support
• Operator training
• After-market service
• Service contracts
• Spare parts provision

UpScale™ – Our Program for a Swift Transition from R & D to Production

Scaled down process experiments are highly important for an efficient design of a given manufacturing process. In this area, Pall offers specific products and technical services to support product development and process design already in the early stages of the product life cycle. UpScale products of the same materials, construction principles and designs enable an easy and rapid scaling to full production. In this way, you can optimize and validate your process swiftly and earlier in the product development cycle.

Pall Scientific and Laboratory Services

Pall’s Scientific and Laboratory Services (SLS) group is well known for its capability for technical support in all aspects of purification and separation technology. Over 400 scientists, technicians and engineers working in more than 40 laboratories worldwide are onhand to design economic technical solutions for the range of challenges set by our customers.
Pall Corporation has offices and plants throughout the world in locations including: Argentina, Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, India, Indonesia, Ireland, Italy, Japan, Korea, Malaysia, Mexico, the Netherlands, New Zealand, Norway, Poland, Puerto Rico, Russia, Singapore, Spain, South Africa, Sweden, Switzerland, Taiwan, Thailand, United Kingdom, United States and Venezuela.

Distributors are located in all major industrial areas of the world.

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