Clear thinking. Clear results.

From research & development through to full-scale bioprocessing, Parker understands the problems faced by biopharmaceutical manufacturers. We are dedicated to providing integrated bioprocessing solutions that are specially developed to reduce your processing costs and ensure product quality and patient safety.
Focused on adding value to your business

The foundations of process improvement

With innovative products, state-of-the-art technical facilities and an international team of specialists, Parker Hannifin understands and supports the specific needs of your process, from research & development through to full-scale production.

Commitment to quality
Parker’s biopharmaceutical products are produced using the latest cleanroom technologies in facilities accredited with the all appropriate quality certification. A strong focus on raw materials and controlled release of products ensures repeatable quality throughout our biopharmaceutical range. We not only welcome but strongly encourage facility audits from bio-manufacturers.

Specialized technical expertise
Parker’s dedicated technical support team is on hand to assist you throughout your entire development process. From system sizing, scale-up and validation through to full-scale process design and optimization, our technical experts work with you to ensure smooth and fast transition between development stages for successful commercialization.

Global support
Wherever you are in the world, Parker is there to help you get the most out of your filtration and fluid management systems. With a dedicated international support team, multiple laboratory and manufacturing facilities, and a network of customer support centres operating in more than 50 countries worldwide, Parker offers you quality support locally.

Dedicated product range
Customer collaboration and a flexible approach to product development have delivered a dedicated, application-based filtration and fluid handling product range for the biopharmaceutical industry. Our customers are an integral part of our product development team leading to focused solutions to meet your present and future business needs.
Media preparation
Optimizing filtration systems

Parker has proven experience of successfully optimizing cell culture media filtration systems at several biopharmaceutical customers.

The sterilizing grade PROPOR HC has been specifically designed for maximum capacity featuring a highly asymmetric integral prefilter layer in an optimal dual layer membrane configuration. In combination with Parker’s single-use mixing technology and bioprocess container bags, the PROPOR HC has reduced filtration system sizes while maintaining rapid batch turnaround time.

![Comparative Performance of PROPOR HC Filters](chart)

*For further details please contact Parker Domeck Hunter*

Custom-designed manifolds
Eliminating contamination risks

Parker understands that every bioprocess is different. We custom-design our single-use systems to meet the individual processing needs of each customer.

Many biopharmaceutical processes use single-use perfusion bioreactor systems which incorporate numerous disposable media bags simultaneously connected to a single bioreactor. To accommodate their unique process, customers are often forced to assemble their own systems.

Parker’s custom moulded manifold and bioprocess container systems prevent product losses and contamination associated with hosebarb failures and increase productivity through reduced system set up time.
Cell culture harvest

Preventing bottlenecks

Parker domnick hunter filtration solutions help leading biopharmaceutical manufacturers find solutions to bottlenecks in small-scale cell harvesting processes.

Premature filter blockage has lead to customers incorporating sedimentation steps at the end of small-scale Chinese hamster ovary (CHO) cell culture runs. Combining the PROPOR HC high capacity dual layer membrane capsule filter with the optimum prefilter from the PROCLEAR range eliminates the need for sedimentation steps reducing the harvesting process time and increasing productivity.

Protecting water systems

Removing diminutive organisms

Specific filtration solutions for purified water systems mean biopharmaceutical manufacturers can enjoy the security of high retention filtration while maintaining flow rates and system size.

The nutrient poor environment of pharmaceutical water systems means waterborne organisms can be small enough to pass through a standard 0.2 micron sterilizing grade filter. The PROPOR LR is directly correlated to Ralstonia pickettii, one of the more commonly found waterborne organisms. It has been specifically designed to remove diminutive organisms from water systems offering higher retention with flow rates comparable to a 0.2 micron system.

Differential Pressure @ 10 L/min (mbar)

- 0.1 µm PVDF
- Typical 0.1 µm PES
- 0.2 µm PVDF
- PROPOR LR
Effective buffer filtration
For faster batch turnaround times

Parker ensures the fast transfer of controlled bioburden buffers and the protection of downstream equipment through effective filtration and buffer preparation systems.

From bioburden reduction to sterilizing grade filtration, the Parker domnick hunter PROPOR range of polyethersulphone filters allows exceptionally high flow rates to prevent delays in buffer processing. These filters are chemically resistant and are compatible with a broad array of process solutions. Integration of PROPOR filters with Parker’s custom manifold transfer systems gives maximum flexibility with minimum assembly time.

Sterile vent filtration
Flexibility in design

Parker’s ability to quickly adapt our products to customer applications allows us to meet specific customer requirements throughout the biopharmaceutical industry.

The design of a sterile gas capsule filter from the market-leading Parker domnick hunter TETPOR range was modified to satisfy a particular need at a global biopharmaceutical customer. The capsules were used as vents on portable stainless steel tanks transporting intermediate vaccine product. Removal of the capsule vent, which was not required, eliminated customer concerns over the vent becoming damaged in use leading to loss of product integrity.

Relative filtration area required to process batch

Comparative Performance of PES Filters

For further details please contact Parker domnick hunter.
Intermediate product filtration

Collaborative product development

Parker is strongly committed to increasing process productivity for our customers. Product development in partnership ensures customer satisfaction and competitive advantage.

The high capacity PROPOR HC sterilizing grade PES filter was developed in conjunction with an insulin manufacturer who was experiencing premature filter blockage when filtering a product intermediate. Initial filterability trials through to full-scale on-site testing and full product validation took less than 6 months and guaranteed full batch processing for the customer. The product has since been incorporated very successfully in various applications at a number of biopharmaceutical manufacturers.

Bioprocess bag systems

Solutions to streamline your process

The sterile transfer of microcarrier beads into the bioreactor can significantly delay biopharmaceutical processes. Parker’s tailored bioprocess bag systems facilitate microcarrier transfer.

Biopharmaceutical customers using microcarrier beads to grow cells in attachment cell culture can find sterilization of the microcarriers a long and difficult task. The microcarriers are often autoclaved in small batches prior to addition to the bioreactor and, as the process is scaled up, this brings even greater challenges.

Parker developed a solution by which microcarriers were sterilized by irradiation within a customized bioprocess bag allowing subsequent quick and easy sterile transfer of microcarrier beads streamlining the process and reducing downtime.

![Total volume throughput (g) vs time (s) comparison of prefilter membranes](image1)

Initial filterability trials on discs: Different prefilter membranes were assessed to determine the optimum configuration for the PROPOR HC high capacity product.

![Total volume throughput (g) vs time (s)](image2)

Initial filterability trials on discs: Improvement over incumbent competitor PVDF sterile filter.
Your trusted development partner
From pre-clinical to commercialization

Parker is dedicated to providing specialized collaboration to support a fast and painless drug development process. Our team can integrate with your own to accelerate your development process and increase speed to market.

Selection & sizing
Selecting the optimum filtration product(s) and determining correct system size is critical to providing maximum process performance. The required final filter type is selected and laboratory-scale testing is performed on discs and/or small-scale devices to establish potential system throughput volumes and optimize any required prefiltration stages.

Scale-up
Following the sizing process, the data generated is utilized to specify a small-scale filtration system, typically composed of capsule filter products, which can be assessed under scaled-down, process-representative conditions. Once confirmation of system performance has been established, the size and format of the required final manufacturing-scale filtration system can be determined.

Validation
Once the optimum filtration system has been identified, Parker domnick hunter will work with you to develop and agree a process validation strategy designed to satisfy any applicable quality and regulatory requirements. Filter qualification testing can then be performed in-situ with our assistance or under simulated process conditions within Parker domnick hunter’s dedicated test facilities.

Process optimization
By adopting a structured process audit approach, we use our extensive knowledge of filtration to further optimize existing filter systems, to provide significant and tangible benefits to process operations such as cost reduction and improved productivity, while ensuring minimal impact upon validated processes. Training packages are also available to support our customers as they develop their personnel.
Parker’s controlled approach to quality ensures your bioprocess is supplied with clean reliable filtration and fluid handling solutions. Our processes, from raw material selection through to final product release, are designed to guarantee reproducible product quality.

Meeting quality standards
All Parker pharmaceutical grade filtration products are manufactured by trained operators using the latest cleanroom technologies in facilities which meet the current ISO 9001 Quality Management System Standard as well as ISO 13485 Medical Device Standard. In addition, we are leading the way through compliance with PS 9100, the application of ISO 9001 GMP guide to pharmaceutical excipients.

Ensuring repeatable quality
Our focus on raw material selection and our extensive supplier quality assurance programme ensures our base materials conform to current regulations such as FDA, CFR’s and cGMP guidelines as well as specifications from our Scientists, Engineers and validation experts. This, together with the use of validated manufacturing and test methodologies, gives high batch-to-batch reproducibility in our products.

A controlled approach
Parker pharmaceutical grade filtration products carry both a lot number and serial number providing full traceability back to base materials. In addition, our products must pass strict lot release criteria before leaving the factory. Regular process audits by trained auditors across the business, as well as extensive customer audits, are performed on a regular basis ensuring the reliability of our quality management systems.

Complete quality assurance
Delivered throughout your bioprocess
Upstream processing

**Bioreactor additions**
Sterile filtration of bioreactor additions such as pH adjustments, antifoam and media feeds with the Parker domnick hunter PROPOR range prevents contamination of cell culture and potential product loss. PROCLEAR filters provide excellent prefiltration where required.

**Media preparation**
Parker can provide tailored growth media preparation solutions for disposable or stainless steel systems. Optimized sterilizing filtration and mycoplasma removal with PROCLEAR and PROPOR filters ensures full batch processing in a timeframe that prevents potential contamination.

**Compressed gas utilities**
Parker domnick hunter is market leader in compressed gas purification and nitrogen generation solutions with a range of technologies and services to guarantee the efficient and trouble free operation of your compressed gas utilities.

**Sterilizing gas filtration**
The Parker domnick hunter TETPOR range of sterilizing gas filters provides effective and economical removal of particulate, bacteria and viruses from bioreactor inlet and outlet gas streams.

**Harvesting of bioreactors**
Effective removal of biomass during bioreactor harvesting or following cell homogenization can be achieved using products from the PROCLEAR filter range followed by bioburden control of the process stream with the PROPOR range.

**Single-use processing solutions**
Parker domnick hunter MURUS and DEMICAP filter capsules can be combined with our disposable mixing technology, bioprocess containers and assemblies for the preparation, transfer and storage of growth media for bioreactors.
Vent filtration
Designed specifically to produce sterile air free from particulate, bacteria and viruses, the Parker domnick hunter TETPOR range is ideal for vent filtration to maintain sterility in buffer and intermediate holding tanks.

Buffer filtration
Parker can provide tailored buffer preparation solutions for disposable or stainless steel systems. Filtration of buffers is essential to protect downstream equipment and ensure the quality of the final product. The Parker domnick hunter PROCLEAR and PROPOR ranges can ensure particulate free and controlled bioburden buffers.

Buffer storage

Sterile filtration

Downstream processing

Steam generation utilities
Parker domnick hunter steam filters have been specifically designed to protect process equipment and pipework from particulate contamination during steam-in-place sterilization of process lines.

Chromatography skid filters
The Parker domnick hunter PROPOR filter range protects chromatography columns and other downstream equipment from bacterial and particulate contamination that can cause fouling and reduce process efficiency.

Intermediate product stream and final bulk product filtration
Parker domnick hunter PROCLEAR and PROPOR ranges have been specifically designed to exhibit low protein binding to ensure minimal wastage of valuable product during the removal of precipitates and bioburden from intermediate product streams.

Single-use processing solutions
Parker’s custom single-use bioprocess solutions can enhance manufacturing flexibility, reduce set up times and minimize process costs increasing batch turnaround time and improving the economy of your process.

Filter integrity testing
Integrity testing of sterilizing grade filters is a fundamental requirement of critical process applications ensuring the biological safety, quality and shelf life of the product. Parker domnick hunter’s PORECHECK IV and VALIARIDATA II units are ideal for pharmaceutical production.

Buffer preparation

Buffer storage

PURIFICATION

BUFFER STORAGE

Sterile filtration

Intermediate product stream and final bulk product filtration

Chromatography skid filters

Vent filtration

Steam generation utilities

Single-use processing solutions

Filter integrity testing

Buffer filtration

Buffer preparation

Formulation

Buffer storage
Filtration Single-use systems

**Products**

**Steam sterilizable up to 225 cycles at 142 °C (287.6 °F)**

- Optimum pleat configuration
- Integral profile layer can considerably filter trains for greater processing recovery

**HIGH FLOW TETPOR II**

- **0.2 micron**
- Optimum pleat configuration
- Unwalled flow rates combined with low pressure drops
- Sintered membranes up to 205 cycles at 142 °C (287 °F)

**PROCLEAR PP**

- **0.6 - 0.6 micron**
- Dual layer media or increased capacity and assurance
- Micron sieve cut-off for protection of downstream membranes
- Ideal for difficult to filter solutions

**PROCLEAR GF**

- **0.6 - 10 micron**
- Excellent air holding capacity
- Non-fibre releasing glass microfibre media
- Long usage life for maximum throughput

**TETPOR AIR**

- **0.2 micron**
- Assured biocompatibility with absolute rated filter
- High flow rates with low pressure drops
- High volume PTFE membrane

**PROCLEAR GP**

- **0.5 - 0.6 micron**
- Dual layer media or increased capacity and assurance
- Micron sieve cut-off for protection of downstream membranes
- Ideal for difficult to filter solutions

**PROCLEAR FF** filters are designed for reliable and economical removal of particulate and microorganisms from pharmaceutical fluids.

**Moulded manifolds**

- Single or multi-use systems tailored to your application
- Proprietary technology allows for any configuration
- No, Tef, titanium, reduces and titanium give maximum flexibility

**Other Parker products**

**PORECHECK IV**

- Designed to fit CER Part 10 and device II compliant environments
- Cost-effective, with disposable growth, and single-use bags
- 180 contaminants test program, defined in blocks

**VALAIRDATA II**

- 3D sensor test regimes for a single 1200 cartridge challenge
- Results correspond to bacterial and viral challenge
- Fully validated secure option design in accordance with GAMP guidelines and the FDA 21 CFR Part 11 requirements

**Filter housings**

- Biopharmaceutical industry standard
- Designed in accordance with international design and sanitary standards

**Gas utilities**

- Compounded air treatment, in accordance with ISO 8573:1
- Filtration, drying, and condensate management
- Tailored on-site nitrogen generation solutions

**HIGH FLOW TETPOR II** gas sterilization filters have been developed to benefit from technological advances with the manufacture of PTFE membranes. This new generation of filters uses the standard with an optimized combination of efficiency, flow rate and strength.

**SpinBag™**

- Universal mixing plate and stand fits 2L to 20L bags
- Small 12” x 12” footprint with integrated heater and variable speed control
- 30 bags, made from flat and can be ordered with custom part configurations

**POGo™ G2 mixing system**

- Effective low shear mixing action
- Fully programmable or manual controls
- Detachable mixing chamber

**DuraPure™ bioprocess bag systems**

- 100 LinkedIn with welded junctions and sanitary fittings
- Available in the following sizes: 200 mL, 2L, 10L, 50L, 200L, 500L, and 1000L
- Incl. P, P, 6-cm 0.2 micron filtered with welded junctions and sanitary fittings

**MURUS and DEMICAP**

- Single-use filter cartridges allow customers to reliably enhance filter retention values into their single-use process streams. This design features low back-pressure resistance and is fully compliant from development to on-bench testing systems.

**Filter housings**

- Biopharmaceutical industry standard
- Designed in accordance with international design and sanitary standards

**Gas utilities**

- Compounded air treatment, in accordance with ISO 8573:1
- Filtration, drying, and condensate management
- Tailored on-site nitrogen generation solutions

**A comprehensive range of compressed air purification solutions guaranteeing the removal of potential 10 contaminants from the distribution system.**