

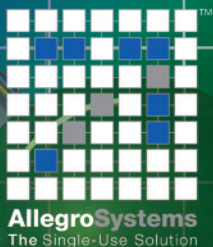


Life Sciences

USD 2472²

Pall Allegro™ Systems

The Single-use Solution for
Manufacturing of Biopharmaceuticals



Filtration. Separation. Solution.SM

Pall Allegro Systems

The single-use solution for manufacturing of biopharmaceuticals

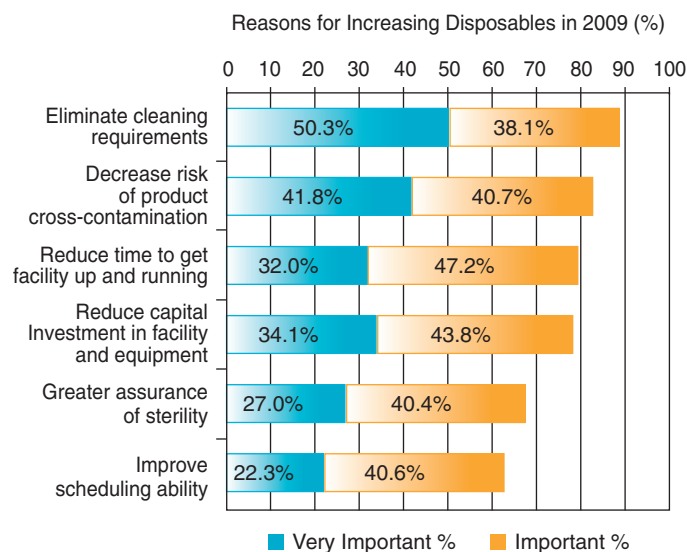
Single-use disposable technology is a proven alternative solution for the biopharmaceutical industry offering several significant advantages over standard reusable stainless steel systems, by reducing:

- ▶ Cross contamination risk
- ▶ Cleaning and associated cleaning validation
- ▶ Capital investment
- ▶ Lead times
- ▶ The number of connections to enhance sterility assurance

Furthermore, in applications where hazardous materials are being processed, such as cytotoxic drugs or potent biological materials, closed disposable systems offer additional protection to operators who are isolated from these hazards.



Reasons for Increasing Use of Single-Use / Disposable System Components



Reference: Report and Survey of Biopharmaceutical Manufacturing Capacity & Production, 2009, BioPlan Associates

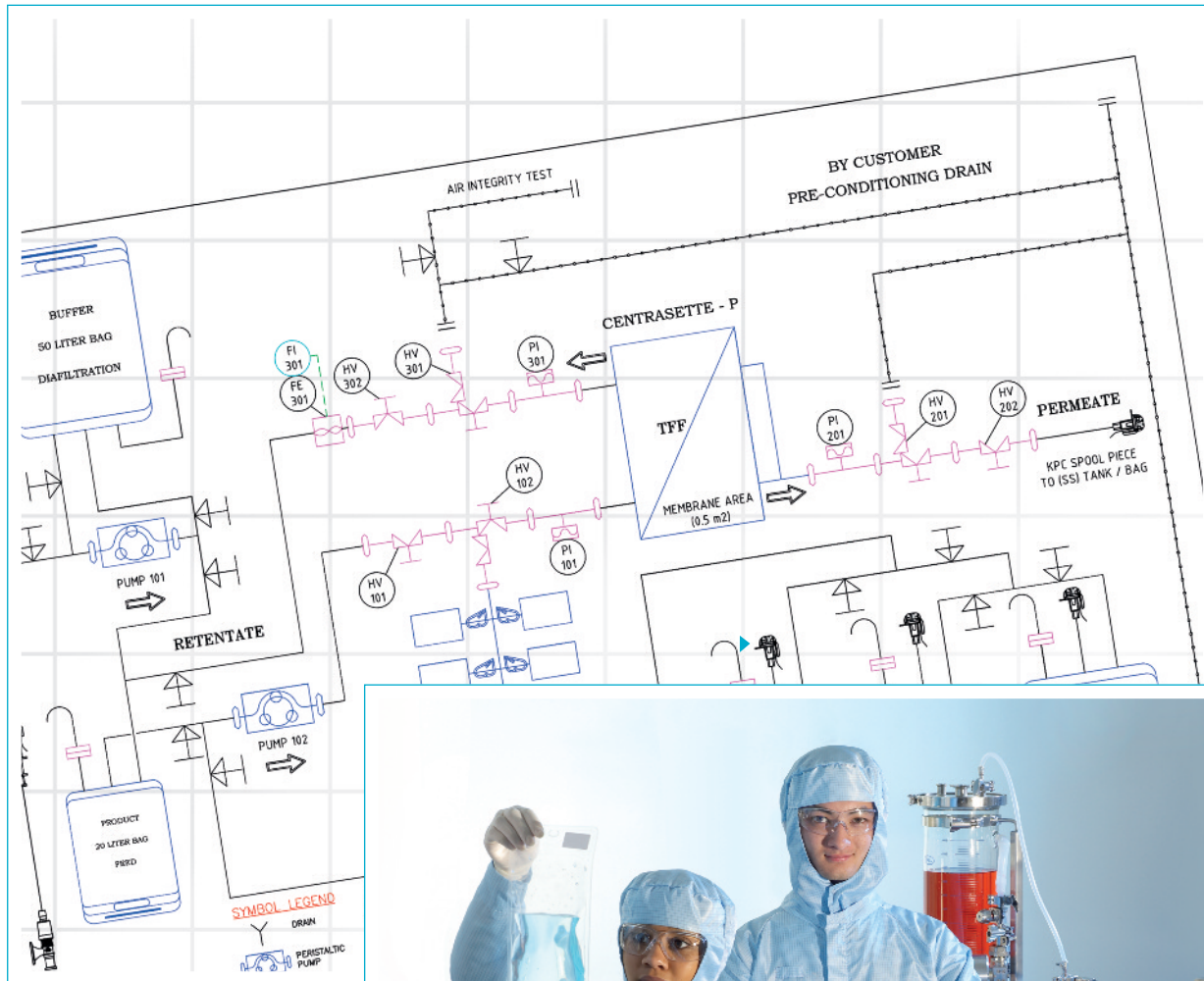
Benefits of single-use systems

- ▶ Cost effective manufacturing technology
- ▶ Flexibility
- ▶ Technology available at all scales
- ▶ Speed of implementation and time to market
- ▶ Suited for all biopharmaceutical processes

Why work with the Pall Allegro systems team

- ▶ Unparalleled process knowledge
- ▶ Significant experience with single-use systems
- ▶ Unique product portfolio
- ▶ Excellence in technical support
- ▶ Full documentation package

We Turn Complex Systems.....



.....Into Simple Solutions

Benefits of Pall Allegro Systems

A cost effective manufacturing technology

While the cost of consumables may be higher, the use of Pall Allegro systems can reduce your overall manufacturing costs by enabling:

- ▶ Drastic reduction in chemicals and WFI consumption
- ▶ Lower energy costs through use of Gamma sterilized components
- ▶ Decreased labor with no cleaning and cleaning validations, faster installations and limited QC testing
- ▶ Smaller space requirements for manufacturing

Flexibility

Pall Allegro systems provide a high degree of flexibility for your process design. They allow you to easily evaluate different configurations before agreeing on the final design. Then, should your batch size be modified, or your requirements evolve, your systems can be easily tailored to fit with your new requirements.

Our technology is applicable to a wide range of unit operations. There will always be at least one step of your process that can benefit from single-use technology.

Technology available at all scales

Pall Allegro systems can be used at many scales, from the manufacturing of small clinical batches to full production scale. Most components are now available at all scales: from capsule filters to chromatography capsules, biocontainers, and all related equipment.

With consistent materials of construction from small to large scale, single-use systems are ideal for scaling up or scaling down your process.

Speed of implementation and time to market

Pall Allegro systems can be developed and implemented in weeks rather than months. Because of the reduced requirements for validation (including cleaning & sterilization) and the ease of manufacturing, process steps can be developed very quickly.

Single-use technology will help you speed up your process development and installation of manufacturing process line, therefore reducing time to market.



Why Choose Pall Allegro Systems

Suited for all biopharmaceutical processes

Pall Allegro systems can be used to manufacture of all types of drugs: monoclonal antibodies, vaccines, gene therapy, recombinant proteins, blood derivatives and anti-cancer drugs. They are particularly well suited for Contract Manufacturing Organizations, where a number of different products will be produced and the key issues are flexibility and avoiding cross contamination.

Single-use technology can be applied from upstream through downstream and formulation and filling.



Upstream

- ▶ Media preparation including mixing, clarification and sterilizing filtration, transfer into biocontainers for storage prior to use
- ▶ Sterile sampling

Downstream

- ▶ Cell harvesting
- ▶ Clarification either with direct flow or tangential flow filtration equipment
- ▶ Capture with single-use membrane chromatography
- ▶ Concentration and diafiltration
- ▶ Contaminant removal with either direct flow capsule filters (virus) or membrane chromatography (virus, DNA and HCP)
- ▶ Buffer preparation including mixing, clarification or sterilizing filtration, and transfer into biocontainers for storage prior to use
- ▶ Sterilizing filtration of bulk and transfer and storage into biocontainers
- ▶ Transfer sets including connectors and vent filters
- ▶ Sterile sampling

Formulation and filling

- ▶ Preparation of the excipients including prefiltration, sterilizing filtration, mixing, and storage into biocontainers
- ▶ Preparation of the final bulk including sterilizing filtration, mixing, and storage into biocontainers
- ▶ Filtration sets for connection into the filling line
- ▶ Single dose filtration system for the preparation of diagnosis products or patient specific products
- ▶ Sterile sampling

Why Choose Pall Allegro Systems

A unique product portfolio to meet all applications

Pall recognizes that single-use systems are becoming the technology of choice for a large number of applications in Biopharmaceuticals processing. We are focusing our resources on the production of innovative disposable technologies to serve the market needs.

As a result Pall has the most comprehensive single-use product line to serve all applications from upstream through downstream as well as filling and formulation.

- ▶ Kleenpak™ connectors that allow the sterile connection of two sterile entities in all types of environments
- ▶ Pall Allegro biocontainers: a large range of process biocontainers with improved features for connection purposes and drainability
- ▶ Capsule filters from very small Acrodisc® units to 30 in. Kleenpak Nova filters with the widest range of filter media and connection capabilities
- ▶ Tangential flow filtration devices in a variety of configurations to match application requirements: cassettes, Microza® hollow fibers, and Kleenpak TFF capsules
- ▶ Chromatography with single-use Mustang® capsules for capture and polishing applications

Unparalleled process knowledge

As the leading solution provider, Pall has been able to create over the last decades a unique engineering team whose role is to build leading-edge systems for the Biopharmaceutical industry. Our Pall Advanced Separation Systems (PASS) team has been involved in the conception, design and manufacturing of simple manual systems to highly sophisticated automated systems that are used throughout the Biopharmaceutical industry.



At Pall, we are using this unique organization to help you to design the single-use disposable systems that you need, making sure that these systems will function according to the process specifications and ensure regulatory compliance.

Significant experience of single-use system assemblies

Pall recognized early on the benefits that single-use disposable technology could bring to the Biopharmaceutical industry. Therefore, over a decade ago and based on our already extensive product portfolio, we established our platform for the design and assembly of single-use disposable systems.

This manufacturing platform for single-use systems allows us to serve our global customer base. We are producing customized non-sterile or pre-sterilized systems that include tubing, connectors, biocontainers, capsule filters, TFF units and more.

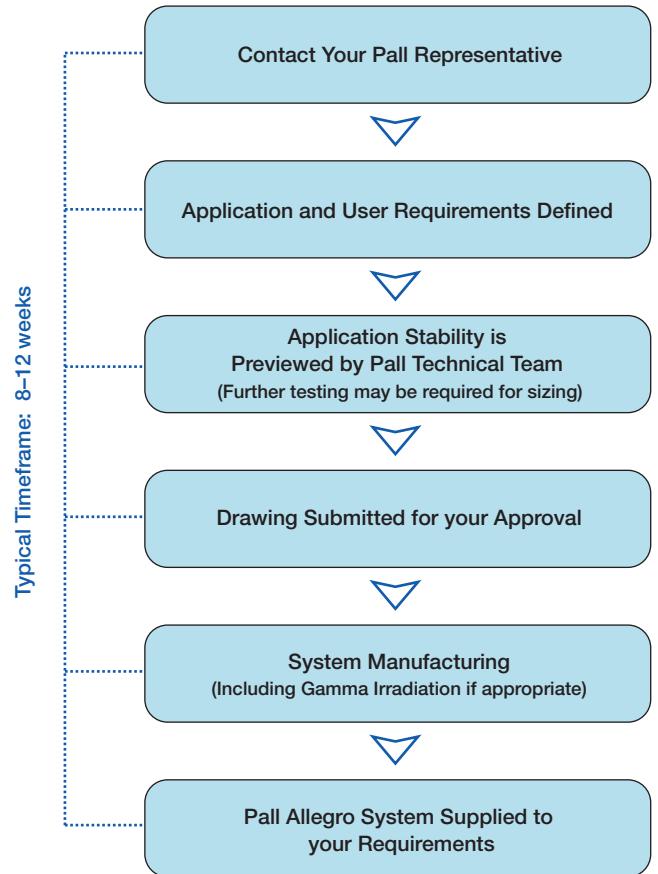


Comprehensive Documentation and Validation

Excellence in technical and validation support

One of the key elements in Pall's customer support operations is the Scientific and Laboratory Services (SLS) group. Pall places its extensive technical resources at the disposal of its customers in the form of world-wide technical advice and training, which will help you to efficiently size, design, and operate your disposable systems. Pall will assist you to meet regulatory compliance through our Validation Services Groups. This can include FAT/ SAT of the system, shipping studies, extractable/leachable studies, and sterilizing filter validation studies.

Order Process for your Pall Allegro System



Comprehensive documentation package

Using our extensive experience of supplying systems to the industry, a full documentation package is available with each system in order to help the end user to build appropriate documentary files to ensure regulatory compliance

- ▶ Certificate of Conformance
- ▶ Drawings
- ▶ Dose mapping report
- ▶ Irradiation certificate
- ▶ Service instructions





Life Sciences

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The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

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