# Single-Use Systems

## Providing Biopharmaceutical Manufacturers with Cutting-Edge Material and Assembly Solutions

**Mike Urbanski**

Recent years have witnessed biopharmaceutical manufacturers transition swiftly from traditional stainless-steel systems that require harsh sterilization between applications to single-use systems (SUS) that are less expensive, faster to produce, and — perhaps counterintuitively — more compatible with sustainability initiatives (**1**). Now that disposable systems have become industry standard, biopharmaceutical original equipment manufacturers (OEMs) are seeking full-service components partners that can offer further innovations in SUS.

### Integrated Solutions

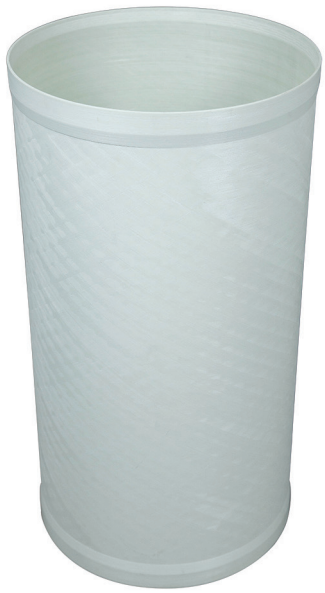
Some suppliers can provide biopharmaceutical OEMs with tailored assembly solutions in addition to finished components. Such work could involve integrating connectors or sensors to extruded tubing assemblies and providing complete system assemblies such as single-use chromatography columns (see the "Chroma — what?" box on the next page). Full-service capabilities enable an OEM to decrease its number of suppliers, helping to improve the overall quality of finished products by reducing the number of systems and processes used and by enabling application of a single quality management system for a complete product assembly. Full service can help an OEM to lower its costs by reducing needs for audits, purchase orders, and shipping and receiving logistics. Vertical integration of services also enables a supplier to understand and rectify all design and manufacturing issues before its products go to market.

When OEMs spend less time and money managing such concerns, they can focus on research and development of materials for manufacture of novel drugs while remaining agile for the future. For instance, they can rely on Trelleborg's BioPharmaPro family of innovative products, materials, and services for single-use fluid-path equipment. The portfolio includes solutions from individual single-use components to assemblies and fully integrated systems for biopharmaceutical manufacturing.

### A Weighty Situation

Traditionally, chromatography-column "shells" have been composed of unreinforced polypropylene (PP), stainless steel, or acrylic. However, such materials are heavy, creating mobility issues. Achieving and maintaining tight tolerances in associated components and seals for fluid distribution can involve significant expenses. Unreinforced PP, stainless steel, and acrylic also are difficult to manufacture at scales needed for commercial downstream processes. Thus, OEMs are seeking alternative column materials that can maintain pressure ratings at high scales without creating concerns for validation processes.

Trelleborg provides significantly improved hardware-material options for chromatography columns with its BioPharmaPro portfolio of products and services. The company's material experts use PP reinforced with continuous fiberglass, which creates a composite material that is lighter and thinner than traditional options (see photo above). The composite can be formed into large-diameter columns that maintain required pressures during chromatography processes. Because BioPharmaPro column shells are composed of the same product-contact material as that used in many columns for research and development and clinical trials (PP), users now can leverage a complete portfolio of PP-based columns for small-scale applications through to commercial production. Such fiber-reinforced composite columns also have a small fraction of the weight and wall thickness of traditional materials.



**Trelleborg experts leverage a reinforced polypropylene (PP) composite material to make thin, light chromatography columns, using significantly less material than is needed for traditional options.**

**Now that single-use systems have become the standard in biopharmaceutical production, suppliers need to offer CUTTING-EDGE solutions and VALUE-ADDING services with an emphasis on sustainability.**

Because Trelleborg uses an additive manufacturing process to produce the columns, they can be made to a breadth of sizes and can include machined features needed for assembly into a functional product. The inner surface finish provides strong sealing, and inner-diameter dimensional tolerances are designed to enable efficient manufacturing. With Trelleborg's cleanroom assembly space and manufacturing capabilities in extrusion, molding, and machining, each chromatography column and its associated components can be made and assembled under one quality and supply-chain system.

## The Quest for Sustainability

Although they seem antithetical to a world trying to move away from disposable components and products, SUS promote sustainability in biopharmaceutical manufacturing by minimizing chemicals and resources (e.g., water and energy) needed to sterilize reusable systems (**2**). Single-use technologies also keep costs and preparation times low. Most important is that SUS nearly eliminate risks of cross-contamination because the product flow path is discarded and replaced after each batch.

Although SUS are a much more environmentally sustainable option than their stainless-steel precursors, biopharmaceutical OEMs are exploring more ways to increase their circularity or ease their end-of-life impacts. As the industry at large continues to grapple with sustainability, suppliers such as Trelleborg remain committed to finding sustainable solutions for single-use materials — e.g., by providing customers with recommendations on how to dispose of or repurpose their used components.

## A Commitment to Driving Supply-Chain Efficiencies

Until recently, any components supplier that could provide single-use technologies to a biopharmaceutical OEM was a valuable partner. Now that SUS have become the standard in biopharmaceutical production, suppliers need to offer cutting-edge solutions and value-added services with an emphasis on sustainability to help OEMs compete in an increasingly demanding market. Proposing innovations in material formulations for existing systems — e.g., chromatography columns — is one example of how suppliers can demonstrate their expertise and value to OEMs. With the BioPharmaPro portfolio of products and services, Trelleborg is committed to being not only a provider of single-use fluid-path solutions, but also an innovator that helps drive supply-chain efficiencies so that patients can receive life-saving therapies more economically and sustainably than ever before.

## Chroma — what?

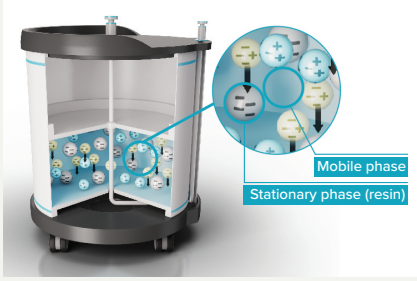
Chromatography columns are systems that use a resin or other such medium to attract or repel molecules. Depending on chromatography-system design and medium chemistry, target proteins can be attracted to the resin while impurities are repelled and eluted, or vice versa. The formats described below represent three broad classes of chromatography.

**Ion-exchange (IEX) chromatography** exploits the reversible exchange of ions between a solid stationary phase and a liquid mobile phase. IEX techniques are particularly useful for separating and purifying charged compounds, such as ions and polar molecules, from complex mixtures.

**Hydrophobic-interaction chromatography (HIC)** involves separation based on target molecules' hydrophobicity. The approach often is used for separating proteins and other large biomolecules based on differences in their tendencies to repel or avoid water.

In **affinity chromatography**, target proteins are attracted to ligands immobilized onto a resin while impurities are repelled.

Affinity chromatography remains the most common approach to purification of protein-based biologics. By having target proteins bind with ligands immobilized on resin beads, impurities can be flushed out. Then, proteins are released from the resin using a buffer that disrupts the molecular interaction.




Chromatography-column hardware plays a key role in providing efficient purification. Flow distributors enable process fluids to disperse evenly around a column's entire circumference, and highly engineered sealing solutions protect valuable resins and fluids from escaping the system. Light-weight materials of construction allow for column prepacking and easy storage before use.

Over the years, significant developments in chromatography resins have created faster, more efficient purification processes. Such efforts will continue for years to come, and chromatography will continue to be a critical part of biologic manufacturing.

## References

**1** Sumant O. *Single-Use Bioprocessing Market Expected To Reach $38.8 Billion by 2030*. Allied Market Research: Pune, India, 2022; https://www.alliedmarketresearch.com/press-release/single-use-bioprocessing-market.html.

**2** Marciniak M. *Single-Use Bioprocessing: Why It Pays Off To Switch to Single-Use Systems Now.* Single Use Support: Endach, Austria, 15 September 2022; https://www.susupport.com/knowledge/single-use-technology/single-use-bioprocessing-pays-switch-single-use-systems.

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