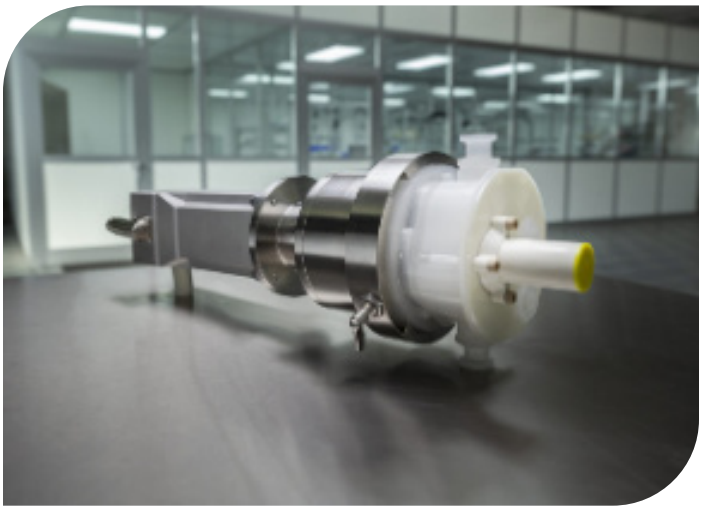
White Paper
Industrial

Advancing pressure protection in biopharma:

How integrated bypass technology elevates single-use pump design

In pharmaceutical and biopharmaceutical manufacturing, there is zero margin for error when it comes to process integrity and operator safety. Among the many variables that must be tightly controlled, pressure ranks high on the list.

Overpressure or vacuum conditions can compromise not only equipment, but also batch sterility, production timelines, and ultimately, patient safety. Robust pressure protection strategies aren't just best practice – they're mandated by regulatory bodies like the FDA and EMA, and central to Good Manufacturing Practice (GMP).



The PureFlo 21 Single Use delivers built-in bypass for smarter, safer bioprocessing.

The case for pressure and vacuum protection

Core systems in biopharma – from bioreactors and buffer tanks to single-use transfer lines – operate within precise pressure thresholds. A sudden spike can rupture vessels or disrupt sterile boundaries, while vacuum conditions can cause structural collapse or introduce air into closed systems.

Without adequate safeguards, the consequences are severe: lost batches, regulatory fallout, and operator risk.

In biopharma production, even a small pressure spike can rupture equipment, compromise sterility, and halt production.

Integrated bypass technology offers built-in protection, reducing complexity and keeping processes sterile.

Standard pressure protection methods

While no single solution fits every application, the most common pressure protection methods can be grouped into three categories. Each offers distinct benefits and trade-offs depending on system requirements:

- **Rupture disks:** rupture disks (or bursting disks) are single-use safety devices engineered to rupture at a predetermined pressure. With no moving parts, they respond rapidly and require minimal maintenance, making them especially suited for aseptic environments. They are compact, cost-effective, and often used where space and sterility are priorities. However, once triggered, rupture disks must be replaced. They can be compromised by improper installation or corrosion, and any released fluids or gases must be safely vented or contained.

- **Relief valves:** relief valves provide a reusable, adjustable method of pressure control. They open at a preset point to release excess pressure and close once conditions return to normal. These valves are widely used in systems that experience pressure fluctuations, offering a high degree of flexibility and reusability. However, they respond more slowly than rupture disks, require regular maintenance and calibration, and can be prone to leakage or performance drift over time.
- **Integrated bypass technologies:** an increasingly relevant category for single-use applications, integrated bypass technologies build pressure protection directly into the equipment itself. These designs simplify system architecture by eliminating the need for external relief valves or rupture disks, instead allowing fluid to be redirected internally when safe pressure limits are exceeded. By reducing system complexity, these technologies support faster changeovers, improved sterility, and greater operational efficiency.

As pressure control requirements evolve alongside the adoption of single-use systems, a new generation of integrated solutions is gaining traction – offering embedded safety without sacrificing speed, sterility, or scalability.

Translating pressure protection into practice

One example of this shift is Xylem's Jabsco PureFlo 21 Single Use pump. Designed with both performance and simplicity in mind, the pump incorporates an integrated, adjustable bypass that automatically recirculates fluid within the pump head when pressure thresholds are exceeded.

This allows the system to recover without disruption, eliminating the need for external relief devices and enabling seamless operation under fluctuating conditions. The pump's self-resetting bypass mechanism helps minimize system downtime by automatically managing excess pressure without manual intervention. Internal recirculation within the pump head maintains sterility and ensures that product integrity is never compromised, even under fluctuating conditions.

Integrated bypass keeps processes sterile and simple.

Xylem's PureFlo 21 Single Use pump has a self-resetting bypass that automatically manages excess pressure, saving time, space, and reducing contamination risk.

Engineering for efficiency and compliance

By eliminating the need for external tubing and hardware, the PureFlo 21 Single Use simplifies system design and validation, reducing setup complexity and risk of contamination. The PureFlo 21 Single Use offers standard pressure relief settings which are factory-calibrated as well as offering custom settings according to customer specifications.

Streamlined design enables faster changeovers and reliable operation.

The PureFlo 21 Single Use incorporates a five-chamber design that ensures ultra-low pulsation, enabling gentle fluid handling even in the most sensitive biologics processes. Its disposable pump head, made of polypropylene, uses less material than comparable designs – offering meaningful environmental benefits without compromising performance.

To support operational agility, the pump features six connection options and a tool-free, click-on interface for fast and secure installation. Each unit is assembled in an ISO 7 cleanroom and produced under an ISO 9001-certified quality system, ensuring reliability and traceability. The integrated pressure relief valve is fully compliant with PED and UKCA standards, reinforcing the pump's readiness for regulatory environments.

A new standard for single-use systems

As biologics manufacturing moves toward faster, more modular production, integrated safety features like those in the PureFlo 21 Single Use offer a compelling edge. By eliminating bulky external hardware, the pump supports smaller system footprints, faster changeovers, and greater confidence in pressure control.

Pressure protection is more than just a regulatory checkbox, it's an opportunity to engineer smarter, cleaner, and more sustainable systems. The PureFlo 21 Single Use delivers on that promise by combining embedded safety, system simplicity, and environmental stewardship in one innovative design.