

**Single-use technologies**

Determining the true cost of single-use fluid management in bioprocessing

A total-cost-of-ownership approach can reveal the true value of quality

Introduction

Efficiency, compliance, and cost pressures continue to challenge biopharmaceutical manufacturers. Organizations are expected to operate leanly, move fast, and maintain quality within a highly competitive landscape. In this context, every product used across the workflow is evaluated for its contribution to these objectives, with assessments often focused on upfront cost. However, small differences in system reliability can translate into meaningful financial impact across manufacturing operations, with hundreds of thousands of dollars in potential annual savings. Focusing solely on unit price, without considering product quality, can mask the hidden costs that determine operational risk and reliability.

Consider single-use bioprocess containers (BPCs) and fluid transfer assemblies—both integral to the production workflow. While these fluid management systems represent a relatively small share of the overall budget, their performance can significantly impact the cost of quality. Differences in leak rates of even a few percentage points can translate into approximately \$400,000 in potential savings of consumables, materials, and labor [1].

The potential for leaks, issues with connection points, limited shelf life, or supply chain disruptions can significantly affect operations, product quality, and process economics. Failing fluid management systems can have disruptive consequences, including environmental health and safety (EHS) issues, corrective and preventive action (CAPA) investigations requiring extensive time and labor, production delays, or even batch loss.

While a lower upfront cost may seem like immediate savings, it can also reflect lower product quality or reduced performance margins, which can increase the likelihood of leaks. In those cases, downstream incidents can quickly outweigh any savings from choosing a lower-quality product. Extended investigations, repeated failures, or high-profile incidents can also impact regulatory compliance.


The bottom line: the true cost of a failure can far exceed the price of the fluid management solution. Total cost of ownership (TCO) goes beyond initial purchase price—accounting for material quality and manufacturing consistency, likelihood and impact of failures, supply chain reliability and replacement lead times, and labor and operational resources required to manage issues.

Quantifying the impact of failures across the workflow

Punctures, particulate contamination, or damaged components identified during incoming inspections of fluid management system products can impose a disproportionate operational burden. Problems with a container or transfer assembly costing just a few hundred dollars can still require up to 30 hours of labor to address, and take around a week to fully resolve [1]. While these events are typically manageable, they impact available resources, interrupt planned activities, and reduce overall process efficiency.

The impact is amplified when issues emerge during setup or active use of the systems. Minor deviations such as improper documentation, incorrect setup, or noncritical functional failures can still create substantial production disruption. These events typically require a minimum of 19 labor hours and can cause up to 4 hours of operational delay [1]. These types of deviations consume valuable operational and quality resources, can stop production for extended periods, disrupt supply commitments, and trigger formal CAPA activities involving cross-functional teams [2].

Operational and financial impact of leak events [1]

-  Each leak event can carry an estimated **\$92,000** in combined costs
-  Up to **30 hours** of labor and **1 week of resolution time** may be needed for one container or transfer assembly issue
-  A minimum of **19 hours** of labor may be needed for even a minor deviation, with up to **4 hours of operational delay**

Quality and reliability are total-cost-of-ownership drivers



Reducing failure rates is a powerful lever for improving the TCO of fluid management solutions. When assemblies perform reliably, leaks, connection issues, and setup errors drop, which leads to fewer deviations, less labor spent on investigations, and a reduced need for corrective actions. This not only reduces disruptions and production delays but also supports more predictable operations, protects product integrity, and helps maintain compliance. In short, investing in quality and reliability up front can enhance reproducibility across the workflow—ultimately supporting greater cost efficiency while safeguarding both timelines and budgets.

This impact is illustrated in the performance of Thermo Scientific™ fluid management systems, which demonstrate lower leak rates compared to industry benchmarks. When applied to a hypothetical cost-of-quality model [1] accounting for consumables, materials, labor, and the risk of batch loss, each leak event can carry an estimated average cost of approximately \$92,000.

When these hypothetical costs are modeled in a manufacturing scenario of 100 batches of monoclonal antibody (mAb) biosimilar per year, at \$2M per batch, Thermo Scientific fluid management systems have an estimated annual leak-related cost of approximately \$761,525, compared to the industry average of approximately \$1,156,050. This difference represents approximately \$400,000 of potential savings in consumables, materials, and labor [1].

In addition to direct cost savings, improved system reliability can reduce deviation investigations, rework, and production delays—supporting an estimated 115 hours or more of labor productivity savings annually [1]. Combined, these savings highlight the potential value of lower failure rates in Thermo Scientific fluid management systems relative to industry benchmarks.

Cost efficiency through reduced leak rates [1]

-  Lower leak rates can translate to about **\$400,000** in potential annual savings
-  Improved system reliability supports an annual savings of about **115 hours** in labor productivity

Incorporating quality-by-design elements

A key aspect of increasing fluid management system reliability and minimizing failure rates is the incorporation of purpose-built and quality-by-design elements. For example, the cable ties typically used to secure fluid connectors have limitations. The ties can snap under pressure, have sharp edges that risk puncturing BPCs, and require extra handling steps such as bubble wrap removal, which can be time-consuming.

In contrast, Thermo Scientific™ BioTitan™ Retention Devices replace cable ties and can enhance the reliability and integrity of tubing assemblies by providing rounded connectors capable of withstanding higher pressures without damaging containers (Figure 1). This design can reduce setup errors, lower the likelihood of leaks and connection failures, and simplify operator handling, reducing extra unpacking steps and supporting sustainable practices by reducing the need for extra protective materials [3,4]. Since launching BioTitan Retention Devices in 2021, secured assemblies have maintained a zero-leak rate at connection points [4], enabling reliable and efficient fluid management. BioTitan devices also reduce operator time. Unpacking a single-use assembly with a 3D bioprocess bag takes roughly 20 seconds, about one-sixth of the time required for a comparable assembly secured with cable ties, which can take around 2 minutes [5].



Figure 1. BioTitan Retention Devices for connections of different sizes.

How supply assurance and shelf life impact total cost of ownership

Reliable product supply is another factor to consider within a TCO assessment. In-region manufacturing of BPCs and fluid transfer assemblies can help shorten delivery times, lessen exposure to tariffs and shipping delays, and support quicker replacement of assemblies in the event of failure. By producing fluid management products close to customers' operations, Thermo Fisher Scientific helps to limit the risk of shortages, maintain uninterrupted production, and reduce operational uncertainty.



In addition, our global standard component library (GSCL)—a globally stocked catalog of standardized, high-usage components—enhances supply assurance by improving inventory availability and enabling more efficient stocking. This standardization can help reduce delivery lead times, mitigate the risk of supply chain disruptions, and support cost optimization, resulting in improved overall reliability for customers. An extended shelf life of single-use BPCs and assemblies also contributes to greater cost efficiency. Most Thermo Scientific™ 2D BPCs, 3D BPCs, and fluid transfer assemblies have a shelf life of approximately 3 years unless limited by specific components, helping to provide flexibility for end users and reliability for procurement teams (Figure 2).



Figure 2. Thermo Scientific™ Labtainer™ 2D BPC with BioTitan Retention Devices.

Longer-lasting products reduce the likelihood of expiration, decrease scrappage, and lower the burden of GMP-compliant warehousing. When assemblies have a longer usable life, drug manufacturers can better manage inventory across multiple sites, avoiding rush orders or wasted materials. This not only reduces direct costs associated with expired products but also streamlines procurement and inventory planning, freeing up resources for other priorities.

Together, supply assurance and extended shelf life contribute to a more predictable, resilient manufacturing operation. By reducing the risks of delays, shortages, and waste, organizations can lower both direct and indirect costs, reinforcing the broader TCO strategy while supporting operational continuity and product quality.

Consider total cost of ownership for a strategic advantage

In today's complex biopharmaceutical landscape, procurement, supply chain, and operations leaders can no longer rely on unit price alone when evaluating fluid management solutions. A comprehensive assessment of TCO, including quality, reliability, labor, supply assurance, and operational continuity, can offer a true measure of value and risk.

Shifting from a price-centric mindset to a TCO perspective helps ensure that the actual drivers of efficiency, quality, and supply reliability are considered when selecting fluid management systems. This broader view underscores the importance of:

- High-quality materials and robust design
- Low leak rates [4]
- Manufacturing consistency
- Increased product shelf life
- Global supply chain redundancy

Even minor disruptions can impact production timelines, quality, and patient supply. Evaluating direct and indirect costs offers a clearer understanding of the operational and financial implications of fluid management choices. A TCO approach captures the full value of high-quality single-use assemblies, going beyond their cost to arrive at a full view of what they enable and what they help prevent.

Our fluid management solutions are engineered to reduce risk, increase efficiency, reduce waste, and help deliver measurable savings along with dependable supply security and continuity.

Incorporating both visible and hidden costs into procurement decisions helps the bioprocess industry strengthen process resilience, safeguard product quality, and maintain predictable, reliable operations.

The full value of a supplier

When evaluating suppliers, consider not just cost per unit but the total cost of quality, assurance, and operational continuity across your workflow.

References

1. Figures are based on internal Thermo Fisher Scientific studies, voice-of-customer interviews, and published industry reports. These figures represent a hypothetical example where real-world historical and benchmarking data have been applied; actual results may vary. Data are based on 95 2D BPCs, 22 3D BPCs, 4 bioreactors, 194 fluid transfer assemblies, and 26 mixer BPCs.
2. Chviruk B, Amherd E, Antonetti J et al. (2017) Transforming deviation management. *BioProcess International* 15(8):12–17.
3. Thermo Fisher Scientific (2022) Comparative analysis of tubing retention devices. Application note. documents.thermofisher.com/TFS-Assets/BPD/Technical-Notes/comparative-analysis-of-tubing-retention-devices-technical-note.pdf
4. Thermo Fisher Scientific (2021) BioTitan Retention Device. Data sheet. documents.thermofisher.com/TFS-Assets/BPD/Datasheets/biotitan-retention-device-data-sheet.pdf
5. Thermo Fisher Scientific. Setup made simple with the Thermo Scientific BioTitan Retention Device. Video. [videos.thermofisher.com/detail/video/6355841068112/setup-made-simple-with-the-thermo-scientific-biotitan-retention-device](https://thermofisher.com/detail/video/6355841068112/setup-made-simple-with-the-thermo-scientific-biotitan-retention-device)

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