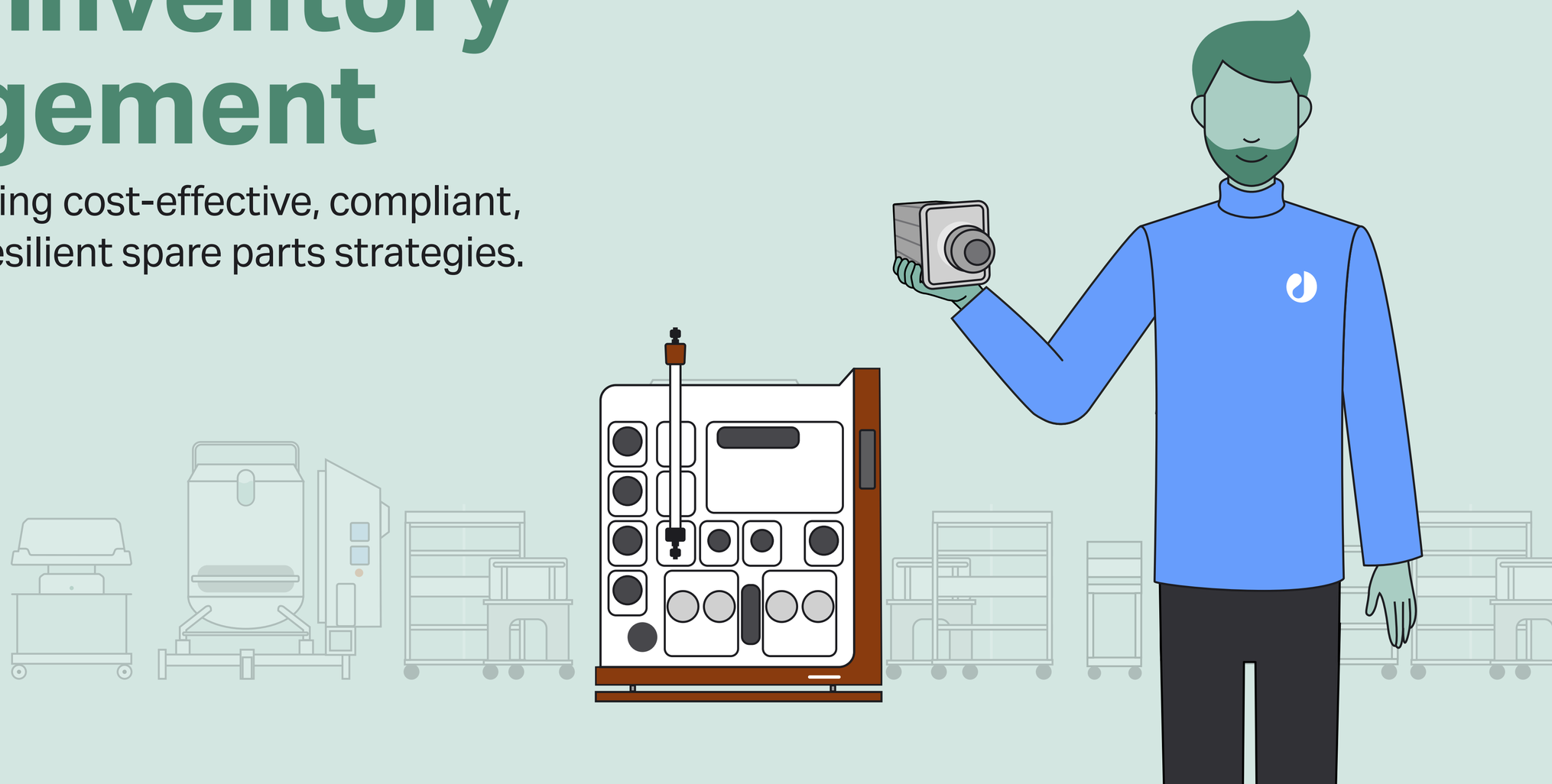
ebook

Mitigating risks with smart inventory management

Your guide to building cost-effective, compliant, data-driven, and resilient spare parts strategies.



cytiva

Introduction

Initially, spare parts management might not seem like the most important aspect of your bioprocessing operations. However, having the right spare parts on site can be the difference between achieving your operational, scientific, and financial goals, or not.

Picture this: you're nearing the end of a crucial bioprocessing production run. Timelines and budgets are tight, and every hour counts. Suddenly, an alarm flashes. A critical component has failed. Now, the frantic mission to source a replacement begins. But what if the part you need isn't in stock? And what if shipping disruptions further delay your production? What if it has to be custom-made, taking months to produce?

Without the right parts on hand, downtime quickly spirals into wasted resources, compromised product quality, missed deadlines, and soaring costs. Years of scientific effort can be undermined. This is why spare parts management matters. In an industry where maximized uptime is essential, investing in your spare parts inventory and having the right strategy for stocking, tracking, and maintaining them helps your operations stay on track.

In this eBook, we explore the key challenges and trends shaping spare parts strategies in bioprocessing. We also share practical tips to help you optimize your spare parts inventory management and future-proof your facility.

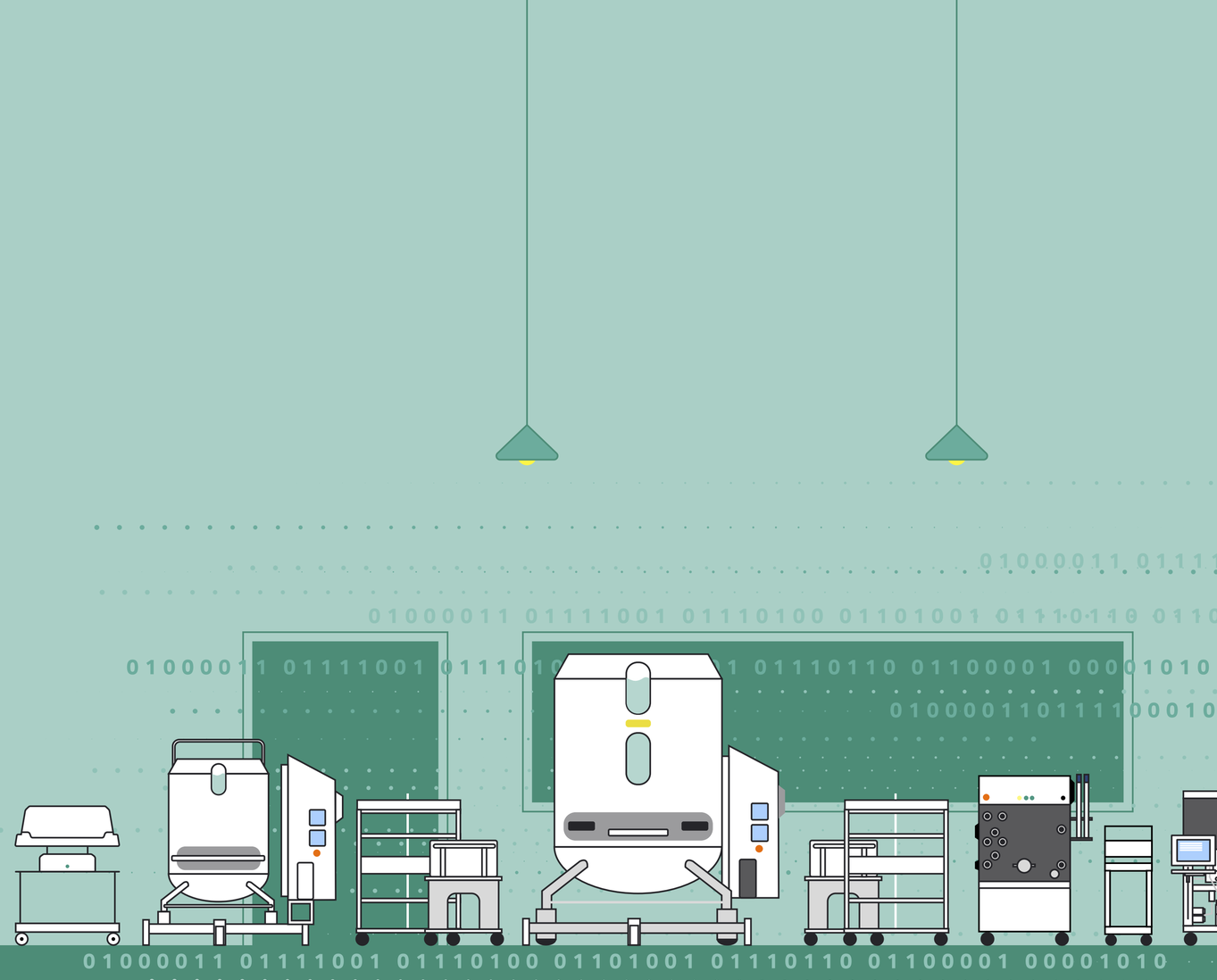


Fig 1. Smart bioprocessing tools for efficiency and compliance.

Shifting toward leaner, smarter, and more compliant inventories

In spare parts management, rising costs, changing regulatory requirements, flexible and scalable manufacturing modalities, and growing sustainability demands mean teams need to rethink how they handle their inventories. The focus is shifting towards leaner, data-driven, and fully compliant strategies that balance cost efficiency with operational resilience. In this section, we discuss the key factors driving this shift and what they mean for the future of your spare parts management strategy.

Cost efficiency

Several macroeconomic factors are making spare parts management increasingly important. Inflation has pushed up the price of bioprocessing components, while global supply chains remain unpredictable – parts can be out of stock for long periods or cost a premium to ship quickly. At the same time, many companies face tighter budgets and cannot afford to tie up money in shelves of unused stock. The risk, however, is that when equipment breaks and the right part isn't available, the delays and downtime end up costing far more.

Moving towards leaner, more strategic inventories means being more selective by keeping the most critical spare parts on hand. This approach helps build an inventory that is cost-effective, while still providing operational resilience for when things go wrong. Over time, this frees up money that can be used elsewhere, cuts down on expensive rush orders, and helps avoid expensive downtime, emergency call-outs, and the knock-on effects of missing important production deadlines.

Evolving regulatory standards

The regulations around bioprocessing spare parts are becoming stricter, with quality and traceability being more important than ever. In the past, many parts were assessed under USP <88> Class VI, which uses an animal-based test to evaluate whether a material causes harm to living tissue. However, this standard is now being phased out because it gives little insight into how materials perform in real bioprocessing conditions or their long-term risks.

The industry is moving to USP <665>[1] , which takes a more scientific, risk-based approach. Rather than relying on a single test, the guidance requires a thorough evaluation of plastic components and systems, including extractables and leachables studies, to demonstrate they are suitable for use.

Depending on your geographical location and application, other regulations may be associated with compliance of spare parts, as described in the following table:

Table 1. Bioprocessing spare parts regulations

Regulation	Role
USP <87> / ISO 10993-5	*In vitro* cytotoxicity tests, designed to check whether materials release substances that damage or kill cells.
ISO 10993 (parts -6, -10/-23, -11)	Broader biological evaluations covering tissue irritation, sensitization, and systemic toxicity, which are now often used instead of USP <88>.
FDA 21 CFR 177	Requirements for polymers used in contact with food and drugs, ensuring materials don't leach harmful chemicals into products.
European Medicines Agency (EMA)/ 410/01 (Animal-derived component free [ADCF] guideline)	Guidance to minimize the risk of transmitting animal-derived diseases by requiring materials to be animal-derived component-free and fully traceable.

To comply with regulations, organizations must confirm every spare part is traceable back to its source and shown to meet consistent quality standards.

1 United States Pharmacopeial (USP) chapter <665> (Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products) is scheduled for implementation on May 1, 2026 https://www.usp.org

Adapting to continuous biomanufacturing

Another key trend in the bioprocessing industry is the shift from traditional batch production towards continuous biomanufacturing, where production runs without interruption. This transition is driven by the need for greater efficiency, lower costs, faster time to market, and consistent product quality (Fig 2).

Despite its advantages, continuous bioprocessing comes with its challenges. This type of production requires specialized, high-precision components built for constant use. Many of these parts are custom-made, meaning they aren't widely available and can't be replaced with generic alternatives.

If a part fails, sourcing or manufacturing a replacement can take weeks or even months, halting production and wiping out the very benefits continuous systems are meant to deliver. To reduce the risk of disruption, companies must maintain a stock of critical spares on site, with special consideration for components that are custom-made or have long lead times. With a strategic, risk-based spare parts inventory in place, downtime is kept to a minimum, and production can keep running as intended.

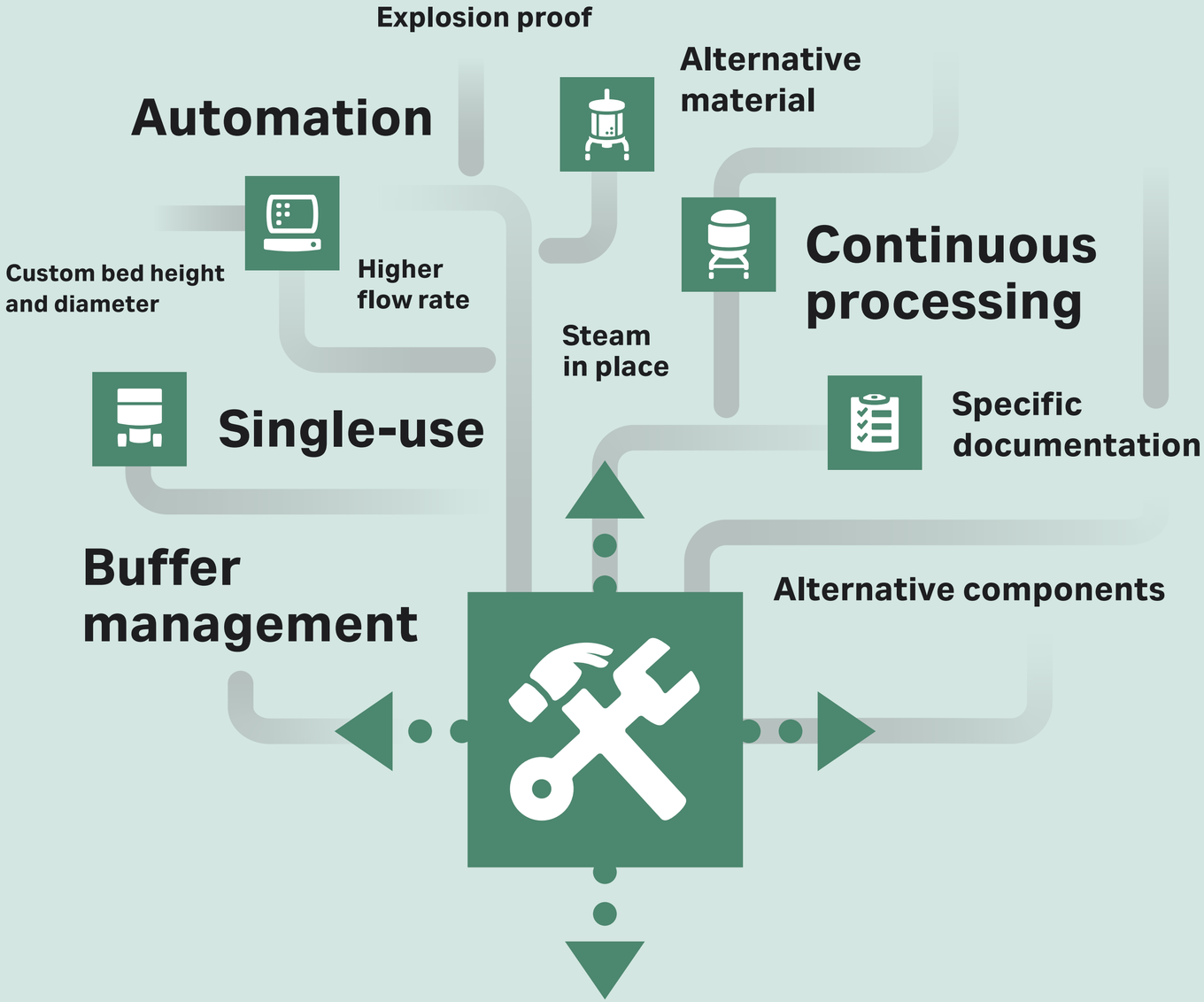


Fig 2. Modern bioprocessing: automation, flexibility, and innovation highlights.

Digitization and automation

As biomanufacturing becomes more complex, companies are increasingly using digital tools and automation to make spare parts management more efficient and reliable. These include centralized inventory systems, using digital platforms that track spare part quantities, locations, and movements, helping ensure critical components are available when needed.

With advanced analytics, AI, and machine learning, these systems can now analyze usage patterns, real-time and historic equipment performance, and supplier lead times to improve inventory accuracy and forecast demand. This offers a much more informed approach to spare parts inventory management, reducing the risk of last-minute scrambles for critical components.

Analysis

- Analysis of the systems
- Your usage profile
- System health checks
- Assessment of current parts stock
- Current maintenance schedule

Report out

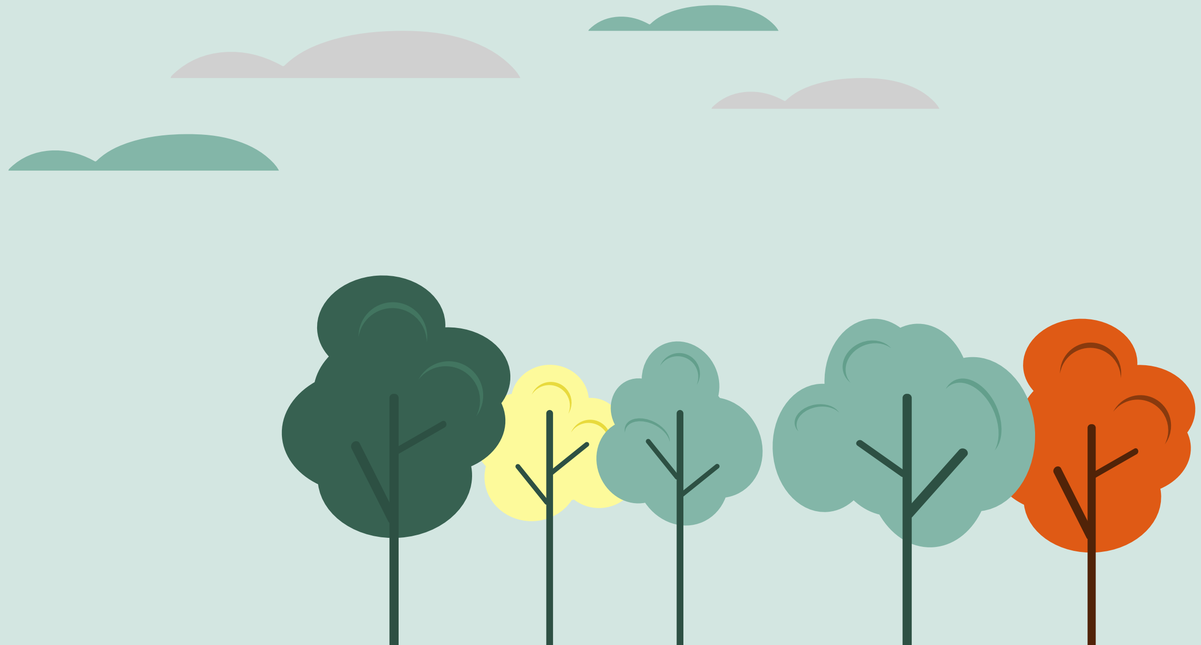
- Summary of your instruments
- Obsolescence and lead time risk
- Consolidated critical spares list
- Prioritization of stocking and quantity levels for installed base
- Upgrade opportunities
- Networking options

Digital platforms also strengthen compliance and traceability. Every spare part can be linked to essential documentation, including certificates, testing results, and regulatory updates, making it far easier to stay audit-ready and reduce the risk of using unverified or outdated components.

Improving sustainability through equipment strategies

Sustainability is becoming a key consideration for bioprocessing facilities, with the increasing need to minimize environmental impact and improve resource use efficiency. Many companies are now building sustainability into their spare parts inventory management strategies. This is achieved by selecting recyclable materials where possible, tracking parts lifecycles, and partnering with suppliers that offer spare parts recycling and refurbishment programs.

In addition to spare parts inventory management, preventative maintenance is also key to improving the sustainability of bioprocessing equipment. This approach helps extend the lifespan of key components, keeping systems operating within manufacturer specifications, reducing wear and tear, and stopping minor issues from escalating into major breakdowns. This translates into fewer replacements, less waste, and reduced transport needs – all of which not only reduce the environmental impact, but also reduce costs and maximize equipment uptime.



Tips to improve your inventory management

Upgrade your manufacturing to smarter, leaner spare parts inventories boosts cost-efficiency, compliance, sustainability, and risk management with the following:

1 Adopt a centralized digital inventory system

The first step to improving spare parts management is moving to a centralized digital inventory system that integrates with your computerized maintenance management system (CMMS). This creates a single source of information, where all inventory data is stored and updated in one place. The benefits include:

- **Real-time visibility:** You can track what parts you have, where they're located, and how they move through your inventory.
- **Traceability and compliance:** Store certificates, regulatory documentation, and supplier information for each part to simplify audits.
- **Collaboration across teams:** Ensure everyone works from the same data, helping to cut down on errors and avoid miscommunication.
- **Centralized control:** Manage logistics, fulfilment, and stock across multiple warehouses or facilities from one platform.

2 Use advanced data analysis and automation

With a centralized system in place, use analytics and automation to turn spare parts management from reactive to proactive, ensuring the right part is always available when needed. Advanced analytics and automation allow you to:

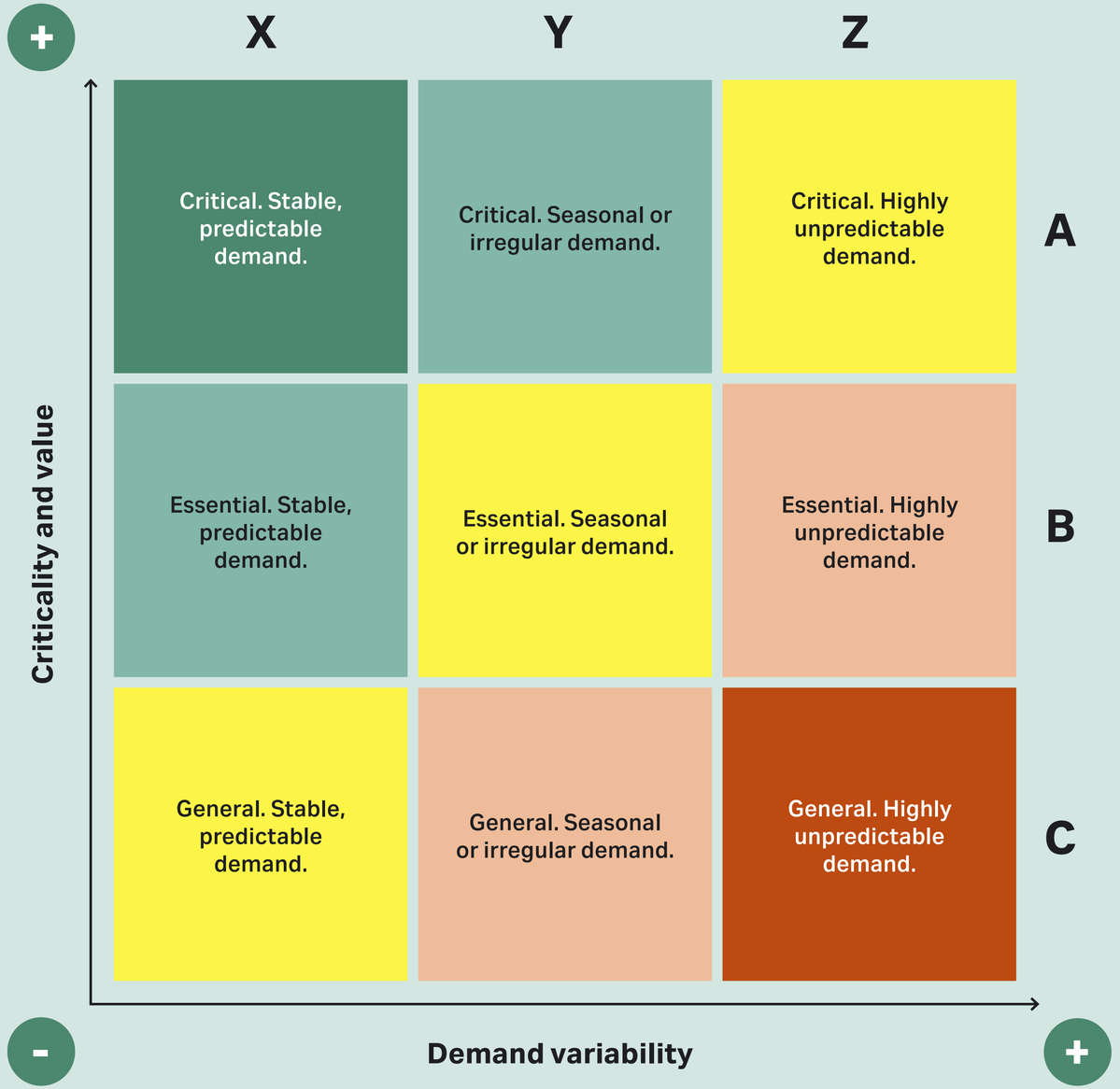
- **Monitor KPIs:** Track inventory turnover, carrying costs, stockout rates, and order fulfilment times to evaluate performance and identify bottlenecks.
- **Automate replenishment:** Set smart reorder points so the system can order parts before shortages occur.
- **Predict demand:** Apply AI and machine learning to combine historical usage, maintenance logs, and sensor data for accurate forecasting.

3 Categorize your spare parts strategically

Some spare parts are more important than others. Ignoring this principle can lead to overstocking the wrong items and understocking the critical ones. Use this structured categorization approach to focus resources where they're needed most:

- **ABC analysis:** Classify parts by criticality and value.
  - **A:** Critical: High-value or custom parts that can cause significant downtime if unavailable.
  - **B:** Essential: Important but less critical items with moderate impact.
  - **C**: General: Low-cost, widely available parts that can be sourced quickly.
- **XYZ analysis:** Add a layer of insight by categorizing parts based on demand variability.
  - **X:** Stable, predictable demand (e.g., filters, gaskets).
  - **Y:** Seasonal or irregular demand (e.g., some tubing assemblies).
  - **Z:** Highly unpredictable demand (e.g., unique sensors or probes).

By combining ABC and XYZ analysis, you can tailor your stocking strategy to create leaner inventories. For example, keep high levels of "AX" parts (critical, predictable) and minimal levels of "CZ" parts (low-value, unpredictable).



4 Train your team

Your systems are only as effective as the people using them. Equipping your team with comprehensive training in spare parts management ensures consistency throughout the team, reducing errors and helping to maintain accurate and up-to-date inventories.

Training should cover the essentials, such as understanding regulatory requirements, using digital systems for accurate logging and tracking, and following qualification and documentation processes to keep parts compliant. Regular refresher sessions can keep knowledge up to date and help the team adapt as regulations or systems evolve.

5 Conduct regular audits and reviews

Even with the best systems in place, errors and inefficiencies can creep into your spare parts inventory. You should conduct regular audits to verify that physical stock matches digital records, documentation is complete, and obsolete or damaged parts are removed. This helps you spot issues before they become costly disruptions and keeps your inventory lean and compliant.

6 Continuously optimize stock levels

Keep your inventory lean but relevant by regularly reviewing stock against demand and maintenance plans. Set clear reorder points to trigger replenishment before shortages occur, and maintain safety stock levels as a buffer against supply delays or unexpected failures.

You should also build obsolescence checks into this process so slow-moving, expired, or discontinued parts are identified and removed. This keeps shelves clear, reduces carrying costs, and ensures every part in your inventory is necessary.

7 Choose suppliers carefully

When choosing a supplier for bioprocessing spare parts, several factors should come into consideration. Instead, prioritize suppliers with a proven record of quality, a secure supply chain, and the ability to deliver consistently at the scale you need. A good supplier should also act as a long-term partner who understands your processes, provides technical expertise, training, and troubleshooting support, and adapts as your needs evolve.

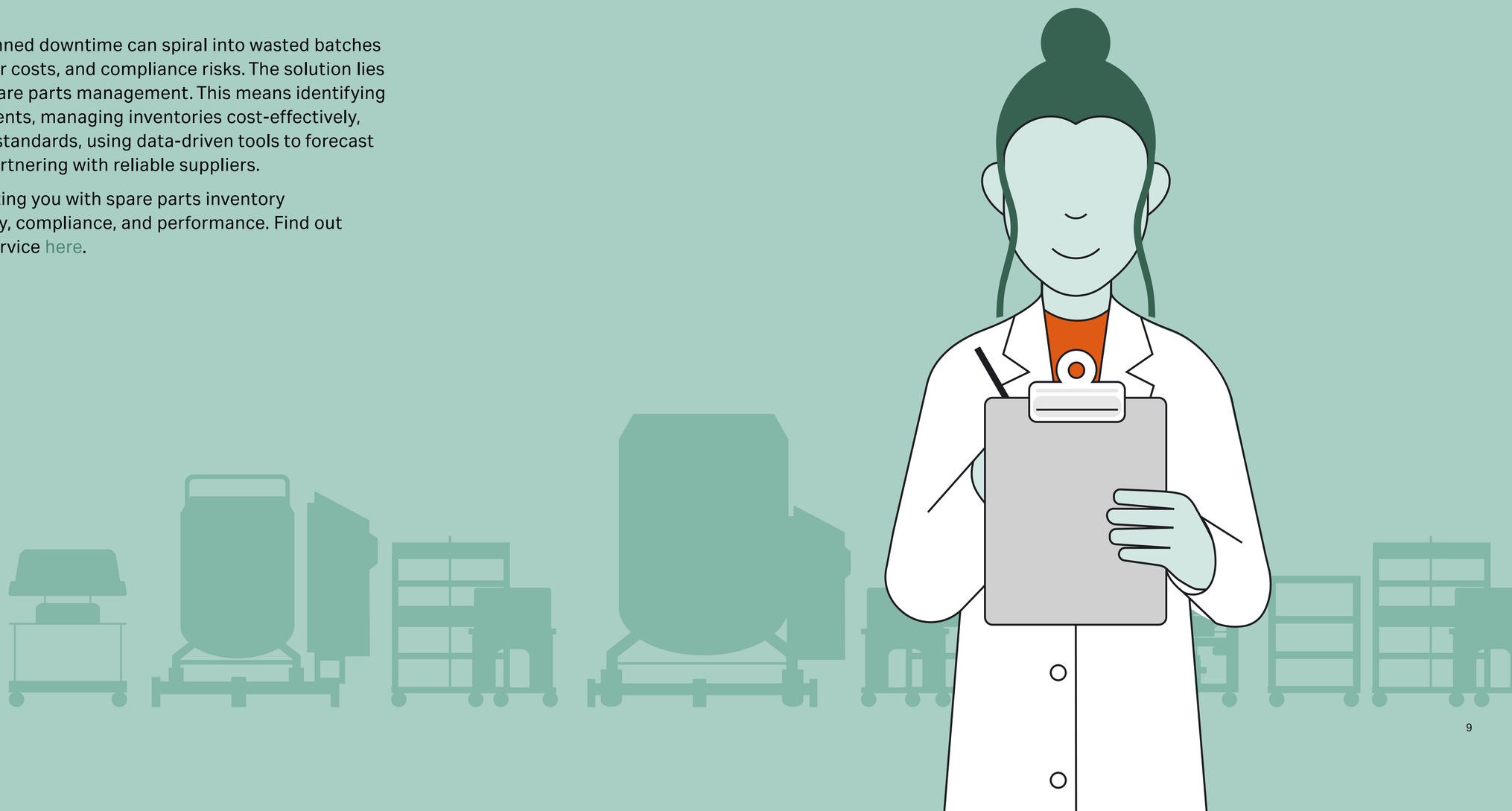
Conclusion

Bioprocessing today is more demanding than ever, with rising costs, unpredictable supply chains, the need for continuous production, stricter regulations, and growing sustainability expectations. In this environment, effective spare parts management is not only about preventing downtime but also about building smarter, leaner, and more resilient operations.

When a critical component fails, unplanned downtime can spiral into wasted batches and resources, missed deadlines, higher costs, and compliance risks. The solution lies in a modern, risk-based approach to spare parts management. This means identifying and stocking the most critical components, managing inventories cost-effectively, keeping pace with evolving regulatory standards, using data-driven tools to forecast demand and prevent shortages, and partnering with reliable suppliers.

At Cytiva, we are committed to supporting you with spare parts inventory management, prioritizing quality, safety, compliance, and performance. Find out more about our spare parts advisory service here.

Read more



cytiva

cytiva.com

For local office contact information, visit cytiva.com/contact

CY56327-17Mar26-EB

danaher