IMPROVE YOUR BIOPHARMACEUTICAL WORKFLOW: SIX BENEFITS OF SINGLE-USE SYSTEM TECHNOLOGIES

In this article, Sara Dorman, Global Biopharma Market Manager at Roquette, discusses the benefits of single-use systems, including how they help accelerate a drug product's journey to market securely and more sustainably.

Bringing valuable drug products to market quickly and safely remains a challenging process. To meet the needs of patients globally, the pharmaceutical industry continues to face pressures to speed up production, scale up manufacturing, simplify workflows and improve efficiencies to lower costs – without compromising on quality or safety. At the same time, implementing robust processes that offer adaptability and fluctuating capacity has become a primary focus for drug developers and innovators, especially in the biopharmaceutical industry.

This was first necessary to meet rising demand for biological therapies, but has become even more pressing following the emergence of covid-19 and the need for rapid and flexible vaccine development.

Single-use systems (SUS) – like precision dispensing technologies – offer manufacturers a way to streamline bioprocessing operations and maximise production efficiencies by increasing throughput and making scalability easier.

TIME TO RETHINK BIOPHARMACEUTICAL WORKFLOWS?

The biopharmaceutical method of developing drugs continues to grow in popularity. It became an especially high-profile topic during the covid-19 pandemic, which necessitated swift manufacture of the mRNA vaccine and monoclonal antibodies for the treatment of the disease, both of which are made using biopharmaceutical processes. This, combined with the global re-emergence of infectious diseases (requiring antibodies) and increased rates of cancer (demanding novel therapies), contributes to the need for more targeted biopharmaceutical therapeutics on the market.

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However, biopharmaceutical manufacture can bring significant operational and technological challenges. Producing these large and complex molecules in a reliable manner at industrial scale requires sophisticated manufacturing capabilities, long process durations, low yields and costly raw materials. Additionally, there is a need for highly skilled operators, making it very expensive to manage production facilities. To meet rising demand for biotherapeutics, there is therefore a necessity for more flexible workflows that allow for rapid scale-up and reduced production costs. Disposable bioprocessing equipment – like SUS – helps to address this and, consequently, it has become increasingly established in the modern biopharmaceutical processing of therapeutic drugs.

WHAT ARE SINGLE-USE TECHNOLOGIES?

SUS refer to disposable biopharmaceutical manufacturing (or bioprocessing) equipment lines, that are designed to be used during the production process of a single batch of therapeutics. Precision dispensing solutions are an example of a SUS, which enables the precise, yet flexible supply of raw materials. An alternative to traditional stainless-steel systems, SUS offer many advantages over reusable and partially disposable systems. This is linked to their unique ability to enhance production flexibility, limit operational costs and reduce overall management of the workflow – while minimising risk of contamination. As such, they are viewed increasingly as a commercially viable approach to achieving maximum process efficiency and productivity during biopharmaceutical manufacturing.

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Single-use (or disposable) bioprocessing systems already dominate the precommercial market, but there is a trend for increased adoption of SUS for commercial-scale manufacturing too. As such, it is predicted that SUS will soon be in place for most biopharmaceutical production lines, especially since the focus on bioprocesses and batch manufacturing continues to grow. This is evident when you consider the numbers. The global single-use bioprocessing market size was valued at US$15.8 billion (£13.1 billion) in 2020 and is expected to expand at a compound annual growth rate of 16% from 2021 to 2028, illustrating the significant uptake of SUS by manufacturers.[1]

Are you keen to understand the reasons behind the rapid adoption of disposable bioprocessing equipment? Here are six ways that SUS, such as precision dispensing technologies, improve biopharmaceutical workflows.

SIX BENEFITS OF CHOOSING SINGLE-USE TECHNOLOGIES

1. Reduce handling time

Traditionally, the process of handling and weighing biopharmaceutical ingredients is time and labour intensive, and requires additional procedures to be put in place, increasing the risk of contamination. The implementation of SUS, like precision dispensing technology, can directly address these challenges. Here, single-use packaging and right-size weighing capabilities can allow processors to discharge raw materials seamlessly into the bioreactor; helping to streamline and eliminate entire steps of the production process, such as clean-in-place (CIP) procedures. As well as increasing efficiencies and limiting risk of cross-contamination, this removes many manual processes that can introduce unintentional human errors, such as weighing raw ingredients incorrectly.

2. Cost savings

Traditional stainless-steel systems are reusable, durable and able to withstand exposure to the powerful chemicals used to sanitise pharmaceutical processing systems. However, because stainless-steel systems necessitate stringent sterilisation regimes, these workflows involve harsh chemicals (which are often harmful to the environment) and result in considerable energy and water consumption. This can be costly and time consuming, while the risk of contamination still remains. Similarly, partially disposable systems – which can be used more than once, depending on the therapeutic being manufactured – must undergo cleaning and disinfection, as well as ongoing maintenance, since they can deteriorate over time.

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Figure 1: A greener, more cost-effective solution: SUS, like precision dispensing technologies, significantly reduce cleaning times, resulting in lower water and energy usage.

SUS are championed for their role in cost reduction largely due to fewer cleaning steps because these systems remove the need for cleaning between every manufacture cycle while ensuring a sterile system for every drug batch, reducing production contamination and generating greater throughput. In addition, SUS can also decrease labour costs, as additional hold times and validation steps can be eliminated. Moreover, with much less facility infrastructure required, including less plumbing or an in-house water-for-injection (WFI) plant, investment and construction costs are lower and the plant's footprint much smaller.

Thus, while SUS require repeated purchase per batch, the costs of these systems are generally offset by the avoidance of cleaning, sterilisation and validation, time saved and improved flexibility versus stainless-steel equipment.

3. Increased productivity

By reducing the amount of time needed for raw material approval, sampling, dispensing and processing, SUS, like precision dispensing technologies (Figure 1), can significantly optimise turnaround times and accelerate the journey to market for novel, life-saving drug products. Crucially, with single-use equipment, process turnaround and set up of new processing lines are much quicker. This links back to the fact that these technologies reduce the significant system downtime needed to clean, sterilise and validate product containers and transfer assemblies, greatly reducing changeover times between processes and batches. Furthermore, this enables facilities to process more batches per year, resulting in increased productivity, efficiency, capacity and profitability.

4. Easily integrated into existing workflows

Equipment like single-use packaging for precision dispensing can be easily and quickly integrated into existing manufacturing processes, and is adaptable across a diverse range of workflows, including stainless steel or hybrid. As such, it provides the flexibility needed to keep pace with the ever-changing pharmaceutical landscape while remaining cGMP and US FDA compliant. Because precision

dispensing offers a "plug-and-play" solution, it also reduces the amount of operations and machinery training required after implementation. In turn, this further reduces the number of hours a facility must invest in material handling and streamlining workflows, bringing more process efficiencies.

5. Better customisation, compliance and control

Packaging for precise dispensing, and single-use pharma charge bags, are designed with the end user in mind and are purpose built to meet exact customer needs. For example, SUS packaging is usually available in a wide range of weights and custom fills, and product features can be matched to the desired chemistries and operational architectures. Packaging and outlet port size can be flexible to suit the application too, with suppliers allowing for customer input and customisation.

In terms of compliance, precision dispensing packaging can be procured from a vertically integrated organisation with a single point of audit, enabling high levels of transparency, easy compliance and extensive in-house knowledge about packaging production and material provenance. There are also two main regulations impacting components used in single-use systems: material biocompatibility and leachables and extractables. Biocompatibility testing requirements fall within USP 87, USP 88, USP 1031 and ISO 10993, depending on the application, while extractable and leachable tests run on the finished products used in SUS. To ensure minimal risk of contamination from the packaging itself, it is important that precision packaging for precision dispensing complies with extractables and leachables regulations for single-use technologies.

6. Promote a greener future

The bioprocessing industry continues to take steps to guarantee a greener, more sustainable future in which resources can be saved, products are profitably used and, at the end of their life, materials are recycled. Single-use technologies exhibit lower environmental impact than reusable systems and are subsequently determined the more environmentally friendly option. This is primarily because they eradicate the need for chemicals and resources – like energy and water – to sterilise reusable systems. Calculations suggest that converting from stainless steel to single use results in an approximate 85% reduction of both water use and waste generation.[2] Furthermore, manufacturers can choose to recycle or repurpose disposables, for example, by incinerating them for energy recovery. As SUS advance further, it is predicted that production efficiencies will continue to improve over time, further reducing their environmental footprint.

A LOOK TO THE FUTURE

As the biopharmaceutical market continues to grow, there is a need for increased efficiencies within existing processes – this requires a rethink of prevailing workflows. With batches needing to be produced more frequently, it will be necessary for biotherapeutic manufacturers to be accurate with their raw material requirements, as well as flexible with their scale-up and scale-down capabilities. To keep pace with these developments while ensuring business profitability and productivity, there will likely be a continued rise in the adoption of SUS – such as precision dispensing technologies – to facilitate the safe and efficient production of specialised pharmaceuticals. And while there will always be a place for stainless-steel and hybrid technologies, the importance of SUS continues to grow.

ABOUT THE COMPANY

Roquette is a family-owned global leader in plant-based ingredients, a pioneer of plant proteins and a leading provider of pharmaceutical excipients. Founded in 1933, the company currently operates in more than 100 countries, has a turnover of €3.9 billion, and employs more than 8,000 people worldwide. Life and nature have been the company's sources of inspiration for decades; all its raw materials are of natural origin and enable a new plant protein cuisine. The company offers pharmaceutical solutions that play a key role in medical treatments and develops innovative ingredients for food, nutrition and health markets, unlocking the potential of nature to improve, cure and save lives. Roquette is committed to improving the wellbeing of people all over the world, and puts sustainable development at the heart of its concerns, while caring for resources and territories in a bid to create a better and healthier future for all generations.

ABOUT THE AUTHOR

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