PALL Life Sciences

The Evolution of Bioprocessing

Continuous Solutions for
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Biopharma's Changing Times

Biopharma manufacturing has advanced significantly over the past few decades. Is continuous bioprocessing the next step?

These are very exciting times for the biopharma industry. Incredible advances are taking place across the field, from new drug delivery techniques that can enhance drug targeting, to the development of personalized cell therapies for treating previously untreatable diseases. But research is not the only area rapidly advancing. Biopharma manufacturing, although still challenging and complex, is becoming increasingly understood as we learn more about how cells work. We are also seeing the development of new technologies that can significantly improve yields and process efficiencies. Perhaps one of the key developments in technology is disposable manufacturing equipment. Although initially viewing such equipment with caution, the industry is now far more accepting after realizing the benefits that single-use systems offer in terms of eliminating the need for cleaning and helping to reduce the risk of contamination. Concerns still exist around extractables and leachables, but again this is a science that is rapidly becoming more understood. Vendors in particular have done much work in this area to help ensure that products are safe.

There is also another key paradigm shift that we are seeing – the move to continuous processing. Continuous processing for small-molecule drugs is being widely discussed in the industry – and even encouraged by regulators, such as the FDA. But what about in bioprocessing? A few years ago, some may have thought that the continuous production of biopharmaceuticals would be impossible given the complexity of working with living cells, but technology is advancing rapidly. Continuous processing in other industries tends to be associated with higher production volumes, but when it comes to the biopharma industry, the benefits in continuous processing are the opposite – the real value of continuous processing for medicine making lies in the ability to produce smaller amounts of drug product in a more flexible and less wasteful manner, which make it ideal given that the industry is increasingly focusing on niche products that do not require enormous production values.

Over the next few pages, experts from Pall discuss the trend towards continuous bioprocessing, as well as other challenges and developments affecting the manufacture of high quality and cost-effective biopharma medicines. Although we live in exciting times, we also live in difficult times. Manufacturers are under enormous pressures to cut costs, which means that better and more cost-effective ways of manufacturing drugs are urgently required. The future impact of continuous bioprocessing is still uncertain, but Pall firmly believe that the technology could help to make a big difference.

Stephanie Sutton
Editor

Stephanie Sutton

Biopharma's Continuous Future

Traditional pharma manufacturers are already dipping their toes in the waters of continuous processing, but what about when it comes to biopharmaceuticals?

There is tremendous pressure on companies to reduce the cost of developing new medicines, while at the same time maintaining high standards for quality and safety. In addition, there is a shift towards flexible manufacturing methods that can readily be duplicated at multiple sites worldwide to enable companies to meet local market needs. It's clear that changes are needed in the bio/pharma industry's manufacturing models – and Martin Smith, Chief Technology Officer at Pall – believes that continuous processing may be the answer.

What trends are driving increased interest in continuous processing for biopharmaceuticals?

For biopharmaceutical manufacturing, process intensification has led to the higher product titers needed to make continuous manufacturing a viable option. Single-use technologies, which are ideally suited for use in continuous operations, are also being more widely adopted at the commercial scale.

Continuous manufacturing can help reduce manufacturing and environmental footprints, as well as manufacturing costs. Continuous processes are monitored on an ongoing basis to ensure that process parameters are maintained at optimal values, leading to more consistent processes and product quality. Smaller bioreactors run for longer times can provide the same quantities of product obtained from batch reactions in large reactors – and a smaller footprint often equates to reduced capital expenditures, allowing for reduced energy, water and raw material consumption, resulting in lower operating expenses. Continuous processes are also more automated, which minimizes human intervention and the potential for error.

There has also been discussion around mobile continuous processing, which could, for example, take place in remote regions of emerging countries or anywhere outside of traditional factory walls. Because of this, technologies that are brought to the market for continuous unit operations should consider both traditional and mobile settings.

"The discussion around continuous processing is very vibrant and I'm seeing keen interest at the unit operation level."

Is continuous processing for everyone?

One factor that is preventing some companies from actively pursuing continuous processing is perceived regulatory uncertainty, but the FDA, in particular, has been an advocate of continuous manufacturing and has been very vocal about the advantages. Perhaps the biggest challenge to continuous processing is the industry's existing infrastructure – and existing processes that are already cost effective are unlikely to be completely converted to continuous. However, there is an opportunity for companies to adopt a "hybrid" system comprising both batch and continuous processes for operations where there is clear evidence that continuous will provide benefits.

In my experience, it is in newer, multi-product, flexible manufacturing facilities that continuous technologies are being more widely implemented, often in conjunction with disposable systems for biomanufacturing. One of the challenges we face at Pall is the wide variation in customer needs and expectations. It is a bit like the Wild West at times because there are multiple ways of doing things. We don't know how it will all play out yet, but we are having many conversations about how the new technologies we are developing can provide the widest applicability range.

Despite the hurdles, the discussion around continuous processing is very vibrant and I'm seeing keen interest at the unit operation level. Most companies, including drug manufacturers and contract manufacturing organizations, have recognized the potential benefits and are at least exploring some aspects of continuous manufacturing. There is no example yet of a completely integrated end-to-end continuous bioprocess on the commercial scale, but people are definitely interested in technology solutions for continuous unit operations. Several biologic drug substances are already being produced using continuous processing (perfusion).

How are new technologies responding to the challenges of continuous processing?

There are three main challenges associated with the implementation of continuous processing. First is the need for cost-effective continuous technologies for some unit operations, such as large-scale filtrations in bioprocessing and continuous crystallization for small-molecule manufacturing. Second is the need for clearly demonstrated performance under cGMP conditions at the commercial scale. Third is the need for process analytical technology that can truly enable real-time analysis of manufacturing processes from end to end. The industry is making great strides in all of these areas, with new developments announced almost daily. Pall has actively expanded its portfolio of continuous bioprocessing solutions and has a number of new technologies under development, as well as some recently launched. For example, our Cadence™ Acoustic Separator (CAS), which is based on acoustic wave separation, was introduced in April 2016 and reduces the buffer volume required to perform large-scale depth filtration by 75 percent. We are also in the process of developing a state-of-the-art clarification solution suitable for use with perfusion processes. In addition to these technologies for specific unit operations, we are looking at technologies to manage waste, as well as being involved in discussions about managing plastic waste.

Gazing into your crystal ball, do you have any predictions for the future of continuous processing?

In the next 3 years, I believe that an increasing number of companies will, to some degree, adopt continuous manufacturing on a commercial scale. Within 5 years, we are likely to see the first examples of fully integrated, continuous biopharmaceutical manufacturing at production scale, and 10 years from now, I believe that continuous manufacturing will be accepted as the norm. I also expect to see continuous processes used for the production of more advanced biological products, such as cell and gene therapies, viral vaccines and virus-like particles. The processing dynamics of such medicines are very different to proteins and antibodies, and both the industry and equipment suppliers will need to develop very specific processes and technologies that can handle these sensitive products.

Is there a risk that late-movers will be left behind?

If a company has a novel drug then they will have a unique position in the marketplace regardless of how it is made. Having said that, it is becoming increasingly difficult for drug companies to get their products listed on insurance company formularies. Payers are expecting differentiated performance at a cost-effective price. Drugs that can't meet both requirements won't be successful in many markets. Therefore, accelerated manufacturing at lower cost is crucial. Early adopters of continuous processing are already realizing the benefits of continuous manufacturing and late adopters could see their product portfolios losing competitiveness.

The benefits of continuous manufacturing have been clearly demonstrated in many other sectors, but these advantages can reach to pharma too! Changes in our industry are driving the need for more efficient manufacturing strategies that consistently provide higher-quality drug products. We are currently seeing the advantages of process intensification and the first steps are being taken to couple unit operations, such as concentration and chromatography, together. As regulatory aspects and the questions surrounding process monitoring are addressed, we will see further movement toward integrated continuous processes.

Breaking the Bioprocessing Mold

Manufacturers have gotten to grips with the complexities of batch-based bioprocesses, but breaking into the realm of continuous bioprocessing can lead to even greater efficiency.

In any production environment, it is generally accepted that there are eight sources of waste: defects, overproduction, non-utilized talent, motion, transportation, waiting, inventory and extra processing. Many industries have reduced their waste by turning to "lean" thinking and "one piece flows" – or continuous manufacturing. Continuous manufacturing can deliver higher productivity and more consistent quality in a smaller footprint, with shorter lead times; and this has revolutionized the automobile industry.

What about the pharma industry? Steps have been made to implement continuous processes for small-molecule drugs, but it's a different story for biopharmaceuticals. For the most part, continuous bioprocessing efforts have been limited to just a few steps, such as perfusion cell culture. Michael Egholm, Vice President/General Manager of Biopharmaceuticals at Pall, believes in much greater potential for continuous bioprocessing.

What inspired your focus on continuous bioprocessing?

Continuous bioprocessing has been a discussion within the industry for a very long time, but nobody has really done anything about it in terms of developing the necessary technologies. The analysis I did with my team showed that the benefits of continuous bioprocessing were so great that someone simply had to do something. We considered our options and decided, about eight months ago, to break the cycle by proactively investing in technologies that help realize the promise of continuous bioprocessing.

Of course, it is easier said than done. Continuous bioprocessing is a difficult field to break into; few companies are using it and few tools are available. As a long-standing supplier of high quality processing systems with a strong and loyal customer base, we knew that we had the technical capability to jumpstart this evolution of the biopharmaceutical industry. Not only is it a big transformation for us, but also for the whole biopharma industry.

What does the industry want from continuous bioprocessing technologies?

Economics are very important, but actually my biggest take-away from all of our customers is that people want robust platforms – meaning that they work every time. Reliability or robustness is desirable for any piece of equipment, but even more so in continuous technologies where the line, by definition, is running constantly. Platform technologies are also key because they keep the continuous process simple and avoid the need for optimization beyond some minor fine-tuning; in other words, implementing a continuous bioprocess is no longer about climbing a huge technology mountain. The technology can be rolled out and implemented quickly.

Some of the critical bottlenecks in both batch processing and continuous processing include centrifugation and/or depth filtration for cell removal and chromatography for primary capture. These are perhaps the least efficient parts of the bioprocess and are not easily convertible into a continuous process. New technology was needed to make this happen. To achieve continuous clarification, we've combined acoustic wave technology with depth filters into a platform technology that works across many different antibodies. The big question: is the industry ready for a full-scale system? It takes time for companies to become comfortable with new technology. Continuous bioprocessing is so new that I think it's important to first give people the opportunity to try out benchtop systems – and to feedback on what they need in a large-scale system.

"There are many advantages to going continuous; reducing waste and cost to name two."

How do you plan to overcome the challenges?

Focusing on continuous bioprocessing has been a significant game changer for Pall. To really understand continuous bioprocessing and to build up expertise, we opened a laboratory at our New England Center of Excellence in 2015. There, we have been running a continuous process all the way from bioreactors through sterile filtration of the purified drug substance. All of this is in a significantly reduced footprint of what it would have taken for batch processing.

I am very proud that we concluded our negotiations with FloDesign Sonics in 2015. We now have an exclusive license for acoustic wave separation technology that allows cell removal or clarification to be performed in a continuous step without a centrifuge. From a regulatory standpoint, the process steps that impact the CQAs (critical quality attributes) in a continuous process are the same as the ones used in batch processing. We've launched three continuous enabling technologies so far: the Cadence Acoustic Separator (CAS) benchtop system (for continuous clarification), the Cadence BioSMB Process Development system (for continuous capture and purification), and the Cadence Inline Concentrator (for single-pass tangential flow filtration) And we've committed to launching more. We have already launched a full-scale version of BioSMB, and later this year we'll be launching a full-scale CAS system and the Acoustic Wave Separation Benchtop for perfusion.

It's a little scary to commit to these dates (but there's nothing like pressure to get something done!). The continuous bioprocessing puzzle requires many pieces and, since the technology is so new, it's crucial that we receive customer feedback to help us further refine the solutions. For example, the feedback we receive from our recently launched benchtop CAS system will be invaluable when it comes to developing the full-scale system. Moreover, the benchtop system also allows users to become familiar with the technology before the full scale system is launched. If we'd just jumped straight into full-scale systems, we could have missed out on an invaluable opportunity to learn about what matters most to the industry.

What do you feel are the main benefits?

There are many advantages to going continuous; reducing waste and cost to name two. And regulators are also keen for companies to review their options – and that includes tools that enable ongoing quality monitoring. Nearly every other industry is using continuous processing so why can't biopharma also use it to achieve greater throughput at lower costs?

With batch-based processing, much of the equipment in a bioprocessing facility stands unused for most of the time. Continuous processing is about using the equipment all the time to perform processes on a much smaller scale, with a smaller footprint (usually around 70 to 80 percent smaller footprint compared with batch processing) – and the lower associated costs.

How has the industry reacted to your focus on continuous bioprocessing?

We've only been talking about continuous bioprocessing for around eight months, but the industry response has been really positive. We're seeing many of the major players taking steps towards continuous bioprocessing – whether it's just one step or the whole gambit. And everyone has their own bias or view on the major hurdles.

The challenges of continuous bioprocessing can only be solved if we work together. Batch-based processing has served biopharma and patients very well, but does not enable further process improvements. Eventually, the industry must update and improve its processes. I don't think everyone will adopt a fully continuous bioprocess stream, but there are some logical steps that can be taken, such as implementing a continuous process just for the clarification step, that can deliver enormous benefits and savings.

When Single Use Meets Continuous Bioprocessing

Single-use technology has made its mark on traditional biopharma manufacturing – now, it promises to help pave the way for continuous bioprocessing.

The biopharma industry can be cautious when it comes to change and new manufacturing technologies, which is understandable given the temperamental nature of cells and the inherent difficulties of biopharma manufacturing. Single-use systems offer a range of benefits including reduced cleaning, increased flexibility and decreased footprint, but many in the industry were wary when the concept was first introduced many years ago. As use has increased, the technologies have become well accepted by users and regulators alike.

Perhaps the main challenge is the limits of scale; single-use systems are generally more suited to small-scale production, but this also makes them highly appropriate for continuous bioprocessing operations. Continuous bioprocessing is a relatively new concept that allows more economical production – but flexible technologies are key to its implementation.

Pall recently announced its intent to focus on continuous bioprocessing and has been exploring options and technologies. We speak to Mario Philips, Vice President and General Manager of Single-Use Technologies at Pall, to find out why single-use systems are key to making continuous bioprocessing a reality.

How have single-use technologies evolved?

Single-use bags have been used in a number of industries for storage, but the biopharma industry has taken this one step further by performing operations, such as mixing, directly inside the bag. At the end of the day, single-use bags are just plastic, but this plastic is highly complex and must also be delivered at a high degree of quality for biopharma applications. Over the last 60 years, Pall has built up a huge credibility in filtration and has gradually moved into single-use technologies. Initially, the company started out with sterile connectors before moving into storage and downstream single-use processing. In 2013, Pall also acquired ATMI's life sciences business, which gave the company access to a portfolio of upstream single-use technologies. More recently, we've gotten involved with continuous bioprocessing and have launched systems for continuous purification (BioSMB), continuous clarification (Cadence Acoustic Separator) and tangential flow filtration (Cadence Inline Concentrator).

The biopharma industry can be quite conservative when it comes to adopting new technologies, but there is no question that single use is getting more mature and is here to stay. Single-use systems are usually combined with stainless steel in a hybrid approach, but some new factories are being built to use single use almost exclusively. In the early days, the biggest challenge for the single-use market was uptake – it's difficult to change the way that the industry does things; the fact that the ultimate end user of biopharma products is the patient means that changes in biopharma are never taken lightly. Today, however, the value proposition of single use is well understood and companies are very comfortable with the technology. In particular, Pall has focused on ensuring that single-use technologies are fit for purpose, as well as being reliable and easy to use; after all, if an operator cannot use and install the system correctly then it's meaningless. When talking about single use, we shouldn't forget about connectors, which also need to be reliable and easy to use.

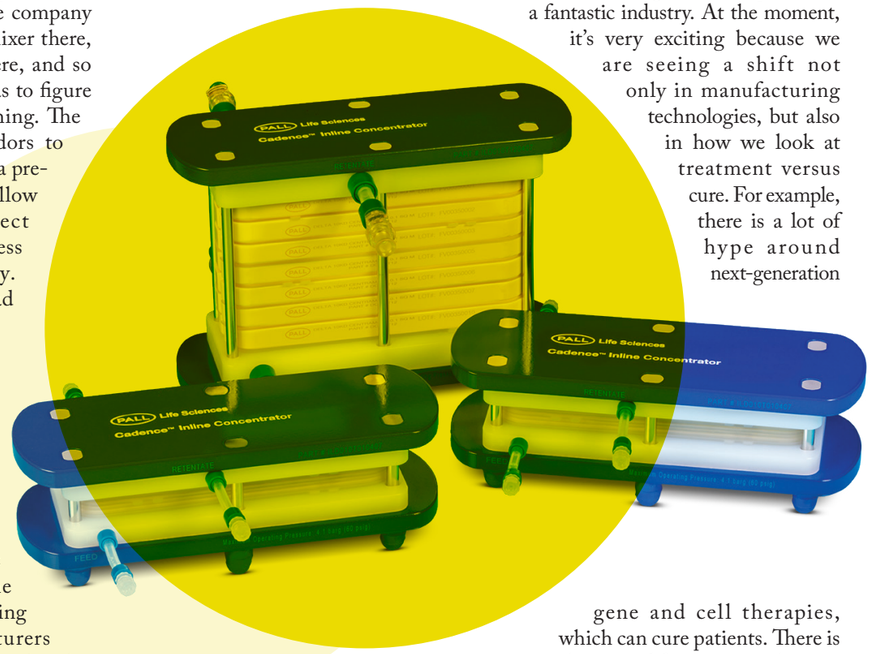
What are the next steps for single use?

Single-use bioreactors have gained a lot of momentum over the past few years. To some extent, single-use tangential flow filtration is seeing more interest too. We're also at the point where some people in the industry are talking about single-use facilities. The market is filled with different customers with different visions and single use is a great way to create more flexibility in a facility. Although some small customers may buy a complete single-use factory, I don't think that large companies will give "the keys of the factory" to just one vendor. When using single-use technologies, you become reliant on vendors for ongoing supply of bags and other components. Most companies don't like to rely on just one vendor, so they typically divide the process up and use different vendors for various upstream and downstream processes, as well as retaining some independence with stainless steel. That said, as single-use technologies have matured and gained greater acceptance, many customers have realized that relying on a large vendor is nothing to be nervous about. A big company like Pall isn't just suddenly going to disappear and is also experienced enough to help ensure a consistent supply of consumables.

However, there is still a lot of work to be done in terms of modular design. As a vendor, we supply the equipment and we can recommend that the company places a bioreactor here, a mixer there, tangential flow filtration here, and so on, but the customer still has to figure out how to connect everything. The next step will be for vendors to help with modular design via pre-fabricated manifolds that allow customers to easily connect everything to get the process up and running quickly. In turn, this will also lead to standardization.

How is single-use affecting continuous bioprocessing?

Continuous bioprocessing has been discussed on and off in the industry for over a decade and there have even been dedicated conferences where everyone came together to discuss the problem – but then nothing happened. Neither manufacturers nor vendors were committing – but this is starting to change. As my colleague, Michael Egholm, discussed on page 6, Pall has taken the decision to try out continuous bioprocessing because we believe in its potential. As a first mover in this field, we are learning a lot and solving many problems, which will help us to be even more innovative in the future. Single-use technologies are a real enabler in moving forward with continuous processing because they can help to make processes more flexible and modular, and are essential for connecting different operations. At the moment, I don't think most companies are ready to go continuous. We are introducing our continuous bioprocessing systems gradually to allow customers to get used to them. At first, I think our customers will use the systems as unit operations but as they become more confident they will start to consider full bioprocessing.



The "sweet spot" for single use is around 2000 liters because larger bags are tricky to handle. Some companies need large volumes, but producing a product continuously means that smaller equipment can do the job. The industry won't need 10,000-liter bioreactors anymore, which saves a lot of factory floor space and capital investment.

What are your thoughts on the future of biopharma?

Continuous bioprocessing will only be used for new products. I don't believe there will be a market for retrofitting an old batch process to a continuous process for a marketed product. For single use, it's a different story because it's relatively easy for companies to replace certain stainless steel unit operations with single use.

I'm sure we all agree that biopharma is a fantastic industry. At the moment, it's very exciting because we are seeing a shift not only in manufacturing technologies, but also in how we look at treatment versus cure. For example, there is a lot of hype around next-generation gene and cell therapies, which can cure patients. There is now a huge need for us, as suppliers, to help scientists realize their dreams. We can never impact the life of a patient in the way that a biopharma manufacturer can, but we can help those manufacturers scale up their operations. I genuinely believe that the future of biopharma manufacturing lies in flexibility – and that means single-use technologies and continuous processing. Pall is no longer a filtration company; we have become a bioprocessing company and our role is to help our customers from a process perspective, so they can concentrate on the science and clinical trials for their treatments.

Enabling Total Biopharma Solutions

A range of integrated single-use technologies are available to enhance biopharma production.

After a few decades of speculation and proof of concept, the biopharmaceutical industry has fully embraced the advantages of single-use technologies throughout all phases of drug production (1). In particular, as industry interest shifts to continuous bioprocessing versus traditional batch methods, the flexibility of single-use technologies has once again emerged as an asset to industry advancement.

Whether using a batch or continuous process, biopharmaceutical developers want to make high quality products in a cost- and time-efficient manner. The ability to translate laboratory-scale processes to commercial, cGMP-compliant production is key to achieving this aim, and the best way of doing this is to use single-use technologies that are designed with scale-up in mind.

Being able to use larger working volumes is also important for efficiency-focused manufacturers. This, combined with the desire for scalability, means that most forward-thinking developers favor technologies that can work across a range of volumes, from the laboratory through to commercial scale (2).

Single-use scale-up

The Allegro™ suite of single-use technologies is specifically designed to allow biopharmaceutical companies to translate development-scale processes into commercial-scale production processes. This portfolio of single-use technologies is fully validated and robust, with easily integrated solutions for upstream and downstream processing, including cell culture, buffer and media prep, up to formulation and filling. Each technology comes with extensive validation packages, including strong manufacturing assembly validation. Users may also request custom validation of the technologies in line to meet specific needs.

Bioreactors and storage solutions

Allegro STR single-use bioreactors are designed for working volumes of 60 L to 2,000 L, making them suitable for process development through to commercial production. The systems are stirred tank reactors that have direct bottom-driven impellers, allowing power inputs up to 0.25 W/kg. This input level reduces mixing times and increases oxygen transfer rates – up to 40 h^{-1} – providing more consistent, scalable performance.

Each bioreactor includes advanced single-use and reusable sensors, with all data recorded in compliance with 21 CFR Part 11, and transmitted to the operator through a user-friendly interface. With clear handling instructions for simple operation, the overall ease of use is industry leading. Compact footprints (height below 3 m) also make the bioreactors a good fit for most cleanrooms.

Biocontainers

The Allegro range also features 2D (50 mL to 50 L) and 3D (50 L to 3000 L) storage biocontainers. These biocontainers are suitable for holding and processing bulk product, as well as for managing and supplying peripheral fluids around unit operations, such as cell culture media, buffer and cleaning solutions.

Allegro biocontainers and their accompanying hardware – including totes and trolleys for transport, storage and handling – are designed to integrate with other systems in the range.

Available in standard configurations that expedite faster qualification following customer evaluation, Allegro biocontainers are designed for ease of installation and use, have enhanced robustness, and are subjected to an extensive validation program. They are also 100 percent leak-tested.

Simple, efficient mixing

The Allegro line features a range of efficient mixing solutions in standard and jacketed (thermal control) stainless steel tote formats – which are both simple and reliable. The line of single-use mixers can incorporate sensors (e.g., pH, conductivity and temperature) and load cells for on-line monitoring and control. Efficient process monitoring and control solutions for mixing steps are easily achieved because the units are designed to be integrated with the Allegro MVP automated single-use system.

The Allegro portfolio also features two magnetic-based mixing technologies:

1. The Pall Magnetic Mixer is a flexible, single-use mixing system with the drive unit located on a portable cart. It is best for solid to liquid applications that require robust mixing steps, such as buffer and media preparation.
2. The LevMixer® system is based on superconductive levitation technology, which causes no mechanical shear or particle generation. It can be used to mix volumes from 10 L to 1000 L across a range of operations, from buffer preparation to final formulation. The unit is capable of directly measuring the impeller speed to ensure process consistency.

For smaller scale mixing, the Allegro line includes the Wand mixer system for product development and cGMP applications. It is capable of mixing from 1 L to 200 L across the five available sizes (5, 10, 20, 50 and 200 L), and is best for applications where portability, high mixing efficiency, reliability, ease of use and a small footprint are required.

Making sterile connections

Connecting units in the Allegro range is also straightforward. All Kleenpak® Presto sterile connectors can be either Gamma irradiated or autoclaved, and because the Kleenpak Presto sterile connectors are made from bisphenol-A (BPA) free polyethersulfone (PES), they are compatible with a wide range of process fluids and solvents.

Kleenpak sterile connectors enable the connection of disposable systems and manifolds – even in an uncontrolled environment – while maintaining the sterile integrity of the systems. Kleenpak II sterile connectors are best suited for high volume sterile fluid transfer in single-use or hybrid systems. For an enhanced level of security, the Kleenpak Presto sterile connector offers intuitive operation that allows sterile connections to be carried out in a simple three-step operation.

System approach to automated processing

Today's drug manufacturers are looking to operate in single-use mode with the same level of reliability and robustness expected from traditional, fully automated process solutions. With the Allegro MVP platform, media and buffer preparation, pH adjustment, membrane chromatography, sterile, depth and virus filtration, viral inactivation and bioburden reduction can all be automated. The platform is designed to enhance flexibility, productivity and product consistency, while simultaneously reducing labor costs and operator errors in upstream and downstream processing.

Users can optimize conditions via configurable, fully disposable flow paths, incorporating single-use sensors for the control of key parameters. The system can also be customized with a large selection of pre-designed manifolds and sensors, connectors, tubing types, filters and pre-filters.

Allegro single-use TFF systems enable fully automated ultrafiltration/diafiltration (UF/DF) processes from 20 L to 2000 L. The compact systems are easy to optimize, ensuring low feed/retentate volumes with the flexibility to run cassette surface areas from 0.5 to 10 m^2. Users have a choice of single-use sensors for feed/retentate and permeate manifolds and 2D and 3D biocontainers for retentate product recovery and buffer/WFI.

Total solutions, total support

Single-use technologies are ideally suited to support the scale up of both batch and continuous bioprocesses from clinical to commercial scale. Single-use technology eliminates the need for cleaning and significantly reduces setup and switch-over times, providing flexibility. Single-use equipment also enables rapid changes in production configurations, schedules and product volumes in response to changing market needs. Furthermore, single-use systems can be readily replicated in multiple locations, ensuring consistent production. Single-use technologies, therefore, mesh well with FDA quality initiatives, including quality-by-design (QbD), process analytical technology (PAT) and continuous processing.

Recognizing the need in the biotech industry for more flexible and efficient manufacturing strategies, as well as the growing interest in continuous manufacturing as a promising solution, Pall Life Sciences has committed to developing single-use technologies that will enable integrated bioprocessing. Because it is essential for new bioprocessing technologies to be scalable, Pall is taking the process development/GMP architecture approach, with the introduction of development-scale solutions that are designed to be further developed at the commercial scale for operation under GMP conditions. The full product offering is backed by onsite custom service support for process development and optimization at any scale or phase of development and production.

Pall Life Sciences has worked to create the Allegro™ portfolio as a broad solution for users, leveraging single-use technology and automation to provide users with enhanced control, flexibility and higher quality end products. To learn more about the Allegro™ portfolio, please visit: www.pall.com/allegro

For a video that highlights Pall Life Sciences total single-use solutions, please visit: https://vimeo.com/205384850

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PALL Life Sciences

Who enables your bioprocess success?

Pall Life Sciences ensures that bioprocess projects succeed with a global network of key scientific and technical experts.

Our team applies over forty years of experience as a leading bioprocess supplier to create the right technical solutions for each customer project, with a focus on optimizing the bioprocess, while minimizing time and cost. Customers have a wide variety of onsite and offsite scientific support solutions to choose from, as well as access to one of our world-class laboratories across globe.

Learn more about how Pall can enable your bioprocesses at www.pall.com/continuousready

Continuously Improving Bioprocesses

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