

Next-generation Aseptic Tech Needed to Cut Contamination Risk

The need for sterile manufacturing conditions in the pharma space continues to rise, increasing industry demand for solutions to help achieve aseptic processing goals without compromising on manufacturing efficiency.

We spoke to Christian Dunne, Head of Sterile Solutions, ChargePoint Technology to find out more about the next generation of equipment designed to help balance the aseptic-efficiency equation.

The Rise in Aseptic Demand

One of the key trends rocking the pharmaceutical industry in recent years has been the booming demand for sterile processing – which rose again this year, despite the economic turmoil of the COVID-19 pandemic. In 2020, the global market for aseptic processing was estimated to be worth \$62.2 billion and is expected to reach a value of \$73.6 billion by 2027¹.

There are a number of reasons for this growing need for aseptic pharmaceutical processing. Chief among them is the rise of parenteral treatments and injectables in particular which, by their nature, must be subject to aseptic manufacturing and packaging in order to safeguard the health and wellbeing of patients. MarketsandMarkets projects the injectable drug delivery market to grow from \$362.4 billion in 2016 to \$624.5 billion by 2021, at a compound annual growth rate (CAGR) of 11.5% during the period².

The rise in demand for these treatments is being driven by growing diagnoses worldwide of chronic conditions, such as diabetes and cancer. As populations in North America and Europe age, and as long-term healthcare becomes increasingly affordable and accessible in emerging economies, such as China and India, we can expect the demand for parenterals to increase further.

In addition, the drive for more patient-centric parenterals is leading to innovations, such as prefilled syringes and auto-injectables, which are further increasing

the popularity of injectable products. Fortune Business Insights' report "Prefilled Syringes Market Size, Share & Covid-19 Impact Analysis," projects the global prefilled syringes market will reach \$10.57 billion by 2027, climbing at a compound annual growth rate of 10.5% during the forecast period³.

These prefilled products also have specific aseptic manufacturing and packaging requirements, which must be met to ensure safety and product integrity.

All of this is driving significant increases in demand for aseptic processing across the pharmaceutical industry. We can expect the need for expanded sterile capacity to continue to rise well into the next decade.

Balancing Aseptic and Efficiency Needs

A major challenge facing pharmaceutical companies looking to meet this new market demand for sterile treatments is how to achieve an aseptic processing environment without compromising on efficiency and productivity.

Failure to reconcile both these challenges could increase manufacturing costs, lowering revenue. Worse, it could impact on return on investment for product innovation, with potential repercussions in terms of resource and appetite for future product development.

With this in mind, there has been considerable innovation in recent years in the technology used in aseptic processing, as well as evolution in drug developer behaviours when it comes to commercialising and manufacturing their sterile treatments. Both of these developments are playing a major part in enhancing the efficiency of sterile manufacturing while optimising product quality.

Outsourcing On the Up

In order to meet growing demand for sterile manufacturing, more and more drug developers are outsourcing to the contract services space.

Contract development and manufacturing organisations (CDMOs) have a unique flexibility to meet aseptic processing goals.

They have the financial resources, specialist expertise, infrastructure and capabilities that many drug developers do not possess in house. This means that they can quickly launch aseptic development, and scale up manufacturing and packaging, helping to achieve the stringent quality standards required while minimising time-to-market. As a result, many sterile drug development projects are now being outsourced to partners.

While such contract partners offer plenty of benefits to drug developers when it comes to expert guidance and support, the outsourcing of production can bring a layer of complexity to the manufacturing process. For example, when outsourcing, drug substances and products often need to be transferred between different facilities and different geographies, all while maintaining sterility. This necessarily creates new potential points of failure that need to be controlled to protect the material from contamination. As a result, manufacturers are increasingly investigating the viability of logistic innovation to ensure the integrity of sensitive ingredients and products during the transport process between sites.

Advances in Aseptic Transit

A number of solutions have been investigated in recent years to support the safe and secure transit of sterile materials between drug development and manufacturing sites.

One of the solutions currently widely used to transport APIs and intermediates is fibre or plastic drums with flexible liners. Despite the benefits they may offer in terms of transit efficiency, these drums do pose challenges when it comes to maintaining sterility during key processes, such as filling, sealing, handling and emptying.

In addition, the processes needed to maintain sterility within the drum during transit require considerable and costly time and resource. This stands in opposition to the overwhelming market need for speedier, more efficient procedures and lower production costs.

In response, drug developers are calling for a new generation of equipment and



processes designed to achieve optimum sterility without any of the efficiency drawbacks of these fibre or plastic drums and other current procedures.

The Benefits of Single-use Technology

For a growing number of drug developers and their partners, the answer to this conundrum is the use of hybrid, single-use technologies in their aseptic processing.

There are a number of key advantages to single-use equipment in sterile pharmaceutical development. They are generally easy to use, with minimal training or production line upgrades required. As they are designed to be used once prior to disposal, they can significantly streamline the hygiene procedures needed to maintain sterility, reducing production downtime and enhancing efficiency. In addition, they can ensure the integrity of products during transit as well as within manufacturing facilities. All of this allows firms to ensure optimum product quality, while helping to maximise process efficiency and reduce production costs.

One key example of a single-use technology that is helping to tackle the twin issues of sterility and efficiency is the split butterfly valve (SBV). These offer a solution for the sterile transfer of powders,

including drug substance and drug product, during the pharmaceutical development and manufacturing process.

SBV technology is made up of two components: an active half and a passive half. The active component is connected to the production line equipment, while the passive half attaches to a filling container. When the two halves of the valve are fitted together, a single plate is created, which allows product to flow from the line into the container via the interior surface of each half, without it coming into contact with the surrounding environment, maintaining the aseptic integrity of the product.

A new disposable version of the passive component of the SBV now exists, which can help achieve the same stringent level of sterile processing while significantly enhancing efficiency. This disposable passive half can be connected to a single-use flexible bag to enable the contained and sterile transfer of pharmaceutical powders between each step in the manufacturing process, as well as between facilities. The passive half doesn't need to be cleaned after use as it can simply be disposed of between fillings, increasing productivity.

These disposable SBV variants are manufactured within an ISO6 cleanroom

environment and are gamma-sterilised prior to use. As such, they are suitable for use in the most rigorous aseptic processing environments.

This new generation of hybrid re-usable and single-use sterile technology can provide a flexible and effective means of aseptic powder transfer, while significantly reducing the costly downtime associated with cleaning, maintenance and validation to maintain a contaminant-free environment.

The Future of Aseptic Processing

This is just one key example of how the pharmaceutical industry is harnessing the benefits of single-use technology to deliver sterile manufacturing while enhancing production line efficiency.

However, there are other exciting areas where innovations are happening to help drug developers and their contract partners to achieve both aseptic and productivity goals. For example, smart monitoring technology is now being integrated into pharmaceutical production lines in order to provide rich real-time data on key equipment performance.

There are two key advantages to this. Having this real-time line performance data can help drug developers generate a rich



audit trail much more quickly. This can allow health and safety teams, and individuals responsible for regulatory compliance to proactively manage the validation programmes for their aseptic lines.

The arrival of smart monitoring technology in the pharmaceutical space has the potential to go even further. It can revolutionise the containment strategies traditionally used in drug manufacturing, by providing manufacturers with a reliable and fully-automated means of understanding the health status of their valves, or other components on their production lines.

This real-time information about every aspect of the production line can help line operatives to identify areas of the production line that need maintenance before they begin to affect productivity, helping them to plan preventative action in a way that minimises downtime. In addition, this data can help them identify where improvements can be made on the production line to enhance product quality and line speeds. Users can access data from their device or using an online dashboard. This can allow for remote data access, so operatives can monitor their lines on the move, or even monitor lines they don't have immediate access to.

Taking all of this into account, it is clear that smart monitoring has the potential to transform operational performance for the better, boosting line productivity while also helping drug developers and their contract

partners to manage risk more effectively. They also offer exciting opportunities to automate and achieve genuine real-time, real-world validation and equipment performance monitoring, giving developers the tools they need to maximise sterility on their drug production lines.

Harnessing the Power of Innovation to Maximise Aseptic Efficiency

The aseptic market has enjoyed robust growth over the last few years, and this shows no sign of slowing down any time soon. A key challenge facing drug developers and their manufacturing partners over the next half decade will be how to meet this demand for sterile production while achieving enhanced manufacturing efficiency.

The pharmaceutical industry is evolving all the time, producing exciting and innovative new therapies and technologies. The question of how to balance sterility and efficiency will only grow more pressing as novel therapies with strict new sterility requirements enter the market, and regulations in key markets evolve to accommodate them. Drug developers will need to be mindful of these and take steps now to future-proof their aseptic processes in order to ensure they continue to meet ever more stringent regulatory requirements.

However, through the use of advanced pre-validated, ready to use single-use solutions which can be effortlessly integrated into their current processes, drug developers and contract manufacturers can be confident they are ready to face this new

world. Armed with the unique convenience, productivity and control benefits of single-use technology, they can ensure they can continue to be competitive and successful well into the future.

REFERENCES

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Christian Dunne is the global product manager at ChargePoint Technology for the sterile containment solutions. For the past 20 years Christian has been creating innovative solutions for the pharmaceutical, biotech, cell therapy and fine chemical industries to overcome high potency containment and aseptic processing challenges. His technical expertise spans high containment isolators, grade A (ISO5) sampling & dispensing facilities, together with R&D and production filling line restricted access barrier systems (RABS) and isolators. For the past six years, Christian has been working with ChargePoint Technology on the advancement of its split butterfly valve technology, designed to handle highly potent/sterile powders and small-scale components, where both product and operator protection are paramount. While working on many aseptic applications, Christian integrated a number of different bio-decontamination systems and consequently has an in-depth understanding of their performance and application. This knowledge was key to the development of the now established ChargePoint AseptiSafe Bio®, used for the transfer of sterile powders in the industry. Christian is an active member of the International Society for Pharmaceutical Engineering (ISPE) and The Pharmaceutical Healthcare Sciences Society (PHSS).