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Preserving the Parenterals of Tomorrow

How the right components, and their manufacturing setup, can meet the needs of an evolving market

Amid the evolution of the pharmaceutical industry, and more recently catalysed by the coronavirus (COVID-19) and its implications on drug demand, delivery and the supply chain, parenteral drugs are experiencing increased demand. Whether administered intravenously, intramuscularly, or subcutaneously, the format creates new and critical avenues for drug delivery thanks to some favourable attributes around safety and efficacy. For one, parenterals allow for a controlled release — either gradual or instantaneous — that an oral medication cannot always provide. This format is critical to providing immediate pain relief, such as with epidurals during childbirth, or for continuously managing fluid levels, such as with saline solutions delivered via IV. Parenterals also encourage patient adherence — often by requiring a clinician for administration — minimising the opportunity for error and the subsequent costly, dangerous consequences.

Still, parenterals cannot perform correctly if the formulas are compromised while in production or en route to patients. Each medication must be safeguarded from the initial phase of manufacturing all the way to the point-of-use. This makes packaging a critical piece of the puzzle in sealing off the drug formula from any outside elements — and ensuring that no leachables from the packaging itself could compromise the integrity of the formulation.

In addition, the market will continue to evolve and bring new drugs into the equation to meet patient needs. Emerging formulas will come with their own sensitivities and requirements for remaining sterile and effective, making that journey to the patient all the more complicated and demanding new measures to prevent contamination. As a result, packaging will play a vital role in the debut of potentially life-saving drugs and will need to be a core consideration in the design and manufacturing process of these new products.

Anticipating the Next Generation of Parenterals

Aiming for zero defects becomes even more critical as highly sensitive parenterals become increasingly common, with injectable biologics in particular emerging as chief drivers of sales growth in the pharmaceutical industry. According to a new study from Market Industry Reports, the sterile injectable drugs market was estimated to be over $500 billion USD in 2019 and is anticipated to grow at a double-digit CAGR from 2019 to 2030.

Considering the potential hazards facing parenterals throughout production and distribution, it may be surprising to learn that the market today still widely uses ampoules — small glass vials — to store and transfer medications. These containers, while offering an appealingly low cost, are susceptible to breakage. If glass particles fall into the drug as a result, the formula may be subject to cause contamination or harm.

On the other side of the spectrum sit prefilled syringes and cartridges, which offer arguably safer transport but have not yet gained traction due to cost and a more complicated design. This type of packaging component, while providing a high-value option with little risk, represents the smallest footprint in the current market.

Yet, the pendulum may swing as the pharmaceutical industry continues to evolve. As a whole, the prioritisation of risk reduction at point-of-use is driving the need for packaging components that enable more fool-proof drug delivery — especially when it comes to self-administered medications. The fewer the steps required, the lower the chance of error.

As a result, personalised medicine is expected to become much more popular and present in the market, as drugs can be designed for more simplified administration and still maintain the necessary level of safety and control. This growth will likely boost the need for prefilled syringes and cartridges — devices that offer one-step use that are easier for both health professionals and patients to navigate. Accompanying these devices will likely be a rise in digital health apps and other technologies that can simplify drug use and self-administration. The result? An increasing need for higher-value components.

Addressing the Changing Demands of Parenteral Packaging

While the adoption of personalised medicines may simplify product use for the patient, these higher-value components also make the manufacturing process more complex. Designing drug delivery to be virtually fail-safe for patients requires an intricacy of safety measures throughout the product packaging.

When working with parenteral drugs in particular, it is important to be aware of potential hurdles posed by problematic packaging and to design production in a way that mitigates these risks. To start with, large-molecule drugs are often more sensitive to particle contamination than small-molecule drugs. This sensitivity can heighten the risk of contamination in the manufacturing process and ultimately render entire batches unusable, leading to major product loss and costs. It also makes the manufacture and packaging of larger batch sizes of drugs like biosimilars and biologics challenging.

This is where the role of packaging components, including sealing solutions, becomes particularly critical. The duty of packaging technologies should be to meet stringent requirements for safety and security throughout the manufacturing process and applying the appropriate sealing solutions to keep parenteral drugs sterile can make the difference in a viable batch. These solutions may take the form of elastomeric plungers—essential features for prefilled syringes, which aim to enhance safety and product integrity by reducing opportunities for error in administration. When designed effectively, plungers provide a smooth glide throughout the syringe barrel. This attribute enables chemical purity by reducing friction and enabling safe administration in manually- or pump-activated syringes — even after long-term storage.

It will be important for these components to modernise in response to the changing needs of drugs. The new characteristics and behaviours of future drugs will dictate new considerations and requirements in drug packaging. As demand increases for large-molecule parenteral drugs, which exhibit significant sensitivity to leachables and other particle contamination, manufacturers can benefit from new innovations in spray coating technologies that enhance the protective barriers of plungers and stoppers. By completely covering such components with a proprietary fluoropolymer spray coating, manufacturers can reduce drug contact with the naked rubber and leachables as well as other external contaminates to better protect formula integrity.

Yet, the trick is not to simply utilise the right components but to also engage the right partner in the implementation of those components. COVID-19 has demonstrated the merits of decentralised supply chains and suppliers that bolster continuous manufacturing capabilities for drug manufacturers, shining a light on service and process — not just materials and component design. New supplier manufacturing capabilities will shape the industry's ability to respond to public health crises and pandemics, and packaging partners that take an integrated approach to design can provide reassurance that foresight and precautionary measures were applied to each level of production.

Achieving a Secure Parenteral Package

To prevent opportunities for contamination throughout production, pharmaceutical companies should work closely with component manufacturers that can accommodate a range of batch sizes and will approach packaging for every product with the same care and scrutiny.

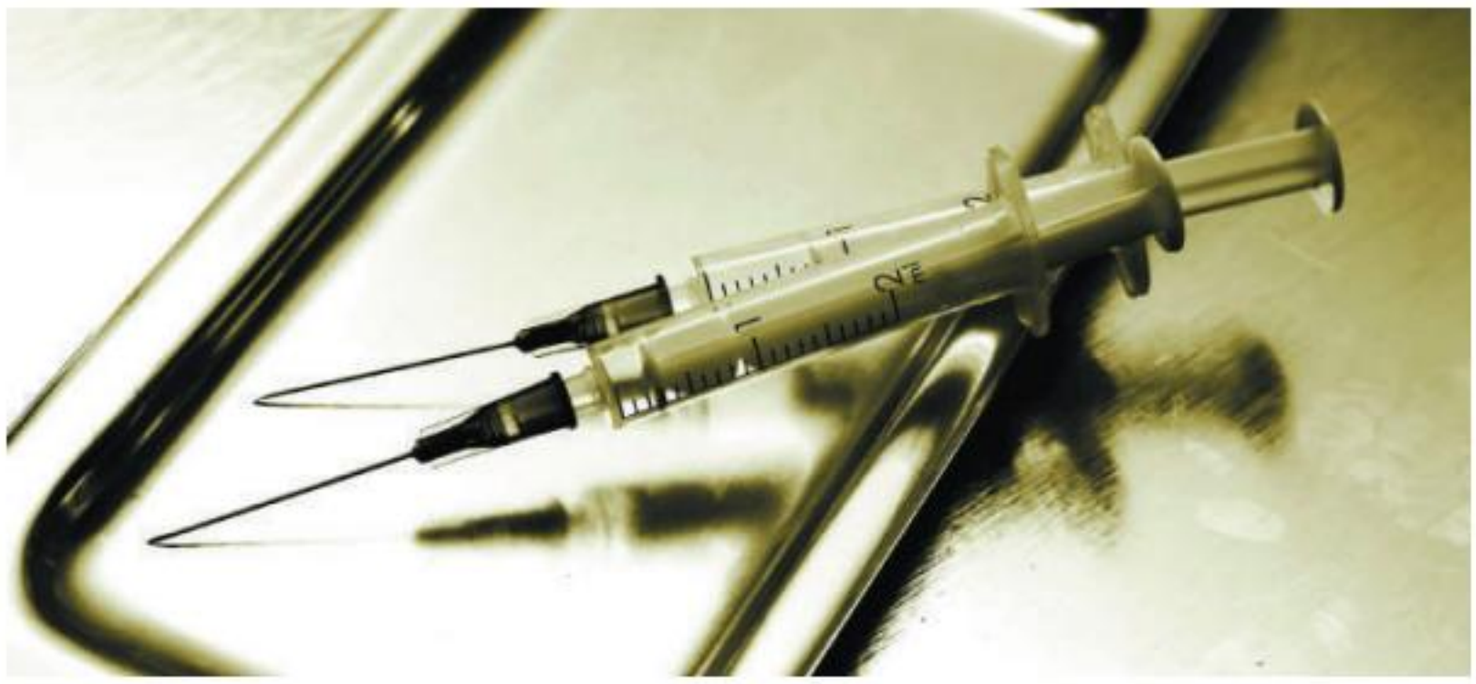
As many companies move toward a modular facility design, flexibility and meticulous attention on the component

Minimising Time to Market While Putting Quality First

Helping drug developers to protect the integrity of injectables throughout development to distribution

Drug manufacturers have always aimed to minimise time to market while also protecting injectables against contamination. However, the challenges COVID-19 has posed to global supply chains have placed even greater emphasis on this goal. According to an FDA study, developing a new medicine takes on average 10 years and costs $2.6 billion from discovery through approval. These are high stakes, so it is essential to utilise every available tool in creating an uninterrupted transition from the development stage to production.

To minimise challenges along this process, drug manufacturers should work with suppliers that offer a "starter pack", with a complete, ready-to-use packaging system to support the development of parenteral drugs. High-performing components should foster sealing compatibility, prevent leaks and alleviate other seal integrity concerns throughout manufacturing and handling. This way, the components offer a comprehensive packaging solution that ensure drug efficacy, stability, and, ultimately, patient safety.



side will be increasingly instrumental in enabling efficiency. Focusing on component sterilisation further upstream in the production process can reduce the manufacturing footprint in a parenteral packaging facility, which can be designed to eliminate the presence of identified contaminants and to meet the highest manufacturing standards.

For one, working with component manufacturers that use camera inspection in their manufacturing process helps add a layer of security the naked eye cannot achieve alone. Cameras do not get tired and do not miss even the smallest anomaly. Among regulators, the trend is continuing toward more stringent standards, pushing drug manufacturers and the designers of packaging and secondary devices to higher levels of scrutiny in manufacturing and design. Ultimately, an adjustable setup also supports the use of automation along the production line to minimise the risk of human contamination.

In addition, pharmaceutical companies will find value in manufacturing processes that can customise packaging to address individual product needs. This is an important capability for complex parenteral drug devices like pump injectors — devices for which off-the-shelf components are often incompatible. In this sense, employing a tailored approach to device design serves as a major avenue for meeting safety and performance standards.

Ensuring Scalability

Agility along the production line may be helpful for preventing contamination and facilitating unique product needs, but it is also helpful for meeting changing market demands. Amid supply shortages for COVID-19 test kits, and speculation on potential shortages of important packaging components for vaccines or treatments, drug manufacturers should scrutinise the processes behind scaling up from development to production. They should take a moment to ask whether a sudden surge in demand would create shortages and capacity limitations in their output. If the answer is "yes", the company should be aware that speeding product to market could result in damaging missteps.

Drug and device manufacturers can mitigate these issues with a few considerations when selecting packaging suppliers. First, select a partner that offers a sample kit or "starter pack" to drug manufacturers that supports easy scaling between development, validation and production. Ensure the partner has expanded, decentralised manufacturing facilities around the globe to meet distribution needs as demand swells.

Next, to harken back to the tailored approach, leverage a combination of batch and continuous manufacturing to provide crucial components in necessary volumes, and closely collaborate to design and quickly produce custom components for effective sealing. Finally, create a manufacturing methodology based around quality control to mitigate defective components that can threaten drug integrity — a fundamental requirement to govern growing operations. As the market continues to evolve, it will be prudent for pharmaceutical companies to consider the types of parenteral products that will gain traction, their individual needs and where component manufacturing will require adjustment to keep up. Flexibility and customisation will serve as important points of differentiation in this process, enabling emerging medicines to reach the patient and perform as intended. The priority for all pharmaceutical companies moving forward should be to engage a partner that can provide a unique manufacturing approach prepared to meet these industry demands — and that can be ready for anything.

Glenn Thorpe

Glenn Thorpe joined Datwyler in November 2017 as Senior Vice President – Pharma in the Healthcare Solutions business. Mr. Thorpe has 21 years of experience in the injectable drug delivery and primary packaging industry. Before Datwyler, he worked in various sales, marketing, business development and general management positions with BD Medical – Pharmaceutical Systems, West Pharmaceutical Services, Unilife Corporation, and SiO2 Medical Products. He is experienced in primary packaging, injectable drug delivery systems, clinical practice, and pharmaceutical industrialisation processes and equipment.