

How the Rise of Biologics is Spurring a Packaging Revolution

Marcelo Cruz at Tjoapack explores the rise of biopharma treatments and explains why, to keep up, pharmaceutical packaging needs to change.

With global sales of biopharma treatments hitting an all-time high of \$300 billion in 2020¹, it is clear that the biologics space is playing an increasingly important role as a driver of growth in the wider pharmaceutical industry. In fact, biologics are expected to account for almost a third of the total value of the global pharmaceutical market by the end of 2023².

The reason why biologics is growing so quickly is simple. The ageing population in North America and Europe, combined with poor diet and environmental pollution in many emerging economies, is leading to an uptick in diagnoses of serious chronic diseases, from auto-immune conditions, to cancer, to diabetes.

More and more, these illnesses are being treated via new-generation biopharmaceuticals, such as monoclonal antibodies. As the global population increases further in the coming years, we can expect demand for these new treatments to continue to grow.

Biologics Bringing Change of Direction for Drug Delivery

The boom in biologics is causing considerable flux in the popularity of a number of common drug delivery methods, and is behind a recent increase in the use of parenteral delivery in particular.

For many biopharma treatments, the only currently effective delivery mechanism is injection. As such, the success of the former necessarily drives the success of the latter.

As a result, the global injectables sector is expected to reach a value of \$624.5 billion worldwide by the end of 2021 – doubling in size since the middle of last decade³.

However, while parenterals necessarily go hand-in-hand with biopharma, they do have one significant downside – they are

not as easy for patients to self-administer as other dosage forms.

Poor useability can have a negative impact on patient adherence, making them reluctant to take their treatment and the right dose and frequency. Drug delivery that requires a professional to administer can also have implications for patient compliance, due to the inconvenience of having to visit the doctor every time a dose is required.

By making injectable drugs easier to use and self-administer, drug developers can maximise the effectiveness of the treatment by supporting patient compliance. They can also relieve pressure on healthcare systems by minimising the need for chronic patients to be seen by doctors.

The Potential of Pre-filled Syringes

Taking this into account, it is imperative for the developers of injectable biopharma treatments to consider ways of making their treatments as patient-centric as possible. A host of companies have invested considerable time and funding in developing new delivery systems designed to support easier self-administered injections at home, and even on the go.

One vital development with the potential to solve this issue is the pre-filled syringe. Coming ready-filled with exactly the right amount of treatment for a single dose, these make it easier for patients to administer their medication themselves without having to measure out their required dose. This saves patients time and safeguards against the consequences of over- or under-dosing. Given this advantage, pre-filled syringes can help drug companies improve patient-centricity to stay ahead of the competition. Nevertheless, the adoption of pre-filled injectables does pose challenges when it comes to production and packaging that need to be tackled in order to maintain optimum manufacturing efficiency.

Tackling Pre-filled Packaging Challenges

There are a number of production and packaging requirements for pre-filled syringes that manufacturers need to consider. Pre-filled syringes in particular

require a clean sterile manufacturing environment in order to protect the health and wellbeing of the patients using them, with specialist equipment and standard operating procedures.

Pre-filled biologic treatments often have additional aseptic processing requirements that must be met. This is because the products involved are generally more complex than those in other dosage media. As such, they often require unique handling to cater for temperature parameters, exposure to oxygen and so on, to ensure both the safety and efficacy of the product.

In addition, pre-filled syringes often have a higher number of components that need to be included in final kits. A staked needle, a loose needle, or even a safety device may be included in the kit, depending on the nature of the treatment within the syringe. Devices may feature a finger flange, or simply have a backstop. The only components that consistently feature are the plunger rod and label.

On top of this, manufacturers may need to include other inserts, such as alcohol pads for sterilising the skin prior to administration, or information leaflets in the secondary packaging to provide patients with guidance on using the syringe.

The Potential of Outsourcing

Taking these packaging challenges into account, it is no surprise that many manufacturers are reconsidering their operations to meet future demand for pre-filled injectables. Many don't have the capabilities or the flexibility in-house to adapt their production lines to address these issues – increasingly, they are exploring outsourcing as an option.

In the past, packaging was considered a low-priority part of the pharmaceutical production process. As a result, companies have often outsourced it to contract development and manufacturing organisations (CDMOs) as part of a broader development and manufacturing service.

However, it is increasingly the case that CDMOs lack the specialised processing



capabilities or the line capacity to meet the complex packaging needs of products such as pre-filled injectable treatments. More and more, we are seeing companies partner with expert contract packaging organisations (CPOs) to fill this knowledge gap, meeting drug companies' specialist packaging needs while reducing cost and enhancing production efficiency.

CPOs are particularly well placed to support the industry in meeting future biologic packaging needs. They have comprehensive expert knowledge of the regulatory environment and the unique processing needs of injectables. In addition, they can offer the flexibility and the capacity to meet every customer's needs. As a result, they can provide drug companies with a customised packaging service that can benefit their businesses over the long term.

Whatever the specific packaging requirements of a treatment, CPOs provide a service that not only optimises efficiency and output, but quality too. This means that they are becoming more than a supplier

of simple transactional services, they are increasingly becoming integral strategic partners that can help pharma companies deliver even better products for patients.

Beyond Packaging

In addition to providing support in scaling up the packaging process for pre-filled syringe products, CPOs can deliver other key benefits that can add further value for drug companies.

For instance, biologic therapeutics have special handling requirements that require stringent chain-of-custody integrity throughout the transport process to where the patient takes possession of the packaged product. CPOs have unique abilities in this area, providing manufacturers with tailored support to account for differing market requirements.

CPOs can provide assistance in a wide variety of transport areas, including vial labelling, re-labelling or over-labelling, serialisation for single or multipacks, or even inventory control. In addition, they can

deliver cold-chain packaging and storage support, to help companies maximise their products' shelf-life and protect the health of patients.

Specialist Partnerships Crucial to Biologics Success

If the biopharma space is to meet future demand for treatments for cancer and other chronic diseases, drug companies need support not just developing their innovations, but delivering the finished products to patients safely and efficiently.

Packaging has a key part to play in achieving this goal. By working with CPOs that specialise in their chosen delivery mechanism, drug developers can benefit from expert knowledge about handling their therapy. They can also enjoy innovative supply chain management support, enhancing efficiency and maintaining regulatory compliance.

With such support, they can be confident their drugs will deliver for patients, transforming their health and their lives for the better.

REFERENCES

1. https://www.manufacturingchemist.com/news/article_page/Trends_and_opportunities_in_biopharmaceutical_product_development_and_manufacturing/170557
2. <https://www.statista.com/statistics/1085563/revenue-chemical-drugs-and-biologics-global-pharmaceuticals/>
3. <https://www.marketsandmarkets.com/Market-Reports/injectable-drug-delivery-market-150.html>



Marcelo Cruz

Marcelo Cruz is Director Business Development and Marketing at Tjoapack. With over a decade of experience in the pharmaceutical industry, and over 15 years of driving global strategic marketing and sales, Marcelo is responsible for the overall Business Development strategy and organic growth activities at Tjoapack. In his role he also leads the development and implementation of inbound and outbound marketing strategies to accelerate lead generation and drive the wider commercial strategy for the business.