MARKET CHALLENGES AND OPPORTUNITIES FOR DELIVERY SYSTEMS AND INJECTION DEVICES

Here, Massimo Mainetti, Head of Strategic Marketing, Datwyler, presents a brief overview of the current state of play in the field of novel biologic medicines as they relate to drug delivery.

The healthcare industry is consistently oriented towards improving patient safety and future health with innovative drugs and treatments. New products and solutions are introduced to the market fast and often clearly indicate in which direction a market or industry is headed. But despite the high frequency, introducing a new and potentially ground-breaking product is a long and highly complex process, especially in the fields of high-end pharmaceuticals and biotech solutions.

The development pipeline for pharmaceuticals and biopharmaceuticals contains numerous promising and innovative treatments with the potential to address unmet medical needs. However, the amount of research and development that is necessary for these new treatments can be tedious, challenging, expensive and subject to substantial scientific and regulatory uncertainty. In fact, on average, only 12% of investigational new medicines entering the clinical trial phase are ultimately approved by the US FDA.

According to PhRMA, about 74% of drugs in clinical development can potentially be considered first-in-class medicines, which is to say that they use a different mechanism of action from any other already approved drugs. Such medicines offer new treatment options for patients, which is key for the care of those who have not responded to existing therapies or for whom no treatment options are presently available.

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The numbers of potential first-in-class medicines in all phases of clinical development are high, but the percentage decreases in the later stages. This is partly because medicines with new mechanisms are less likely to make it through the development process due to higher levels of uncertainty. Among others, these uncertainties include the chemical composition of the drug and the reaction potential with interacting materials such as packaging components or other external factors. Therefore, primary packaging and the method of administration are crucial for the success of the drug product.

Due to their nature and composition, many of these innovative drugs – especially biotech drugs – tend to be administered by injection. To ensure the efficacy and integrity of the drug, the packaging components have to meet the highest regulatory standards of the industry. However, with the fast development of new medicines, the requirements for parenteral primary packaging are ever-evolving and constantly changing, especially in the growing field of biosimilars and biologics. At the same time, novel injection devices have been emerging fast.

For these new treatment options, prefilled syringes and innovative injection devices for at-home use have become the go-to choice for administration, especially for chronic

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diseases, as they provide patients with more comfortable and flexible treatment options. To ensure the integrity of the contained drugs at all times, the right choice of primary container, elastomer closure, coating technology and aluminium or plastic outer seal is crucial in drug development and across the entire lifecycle of the drug – from development and manufacture, through transport and storage, to the application. Elastomer components especially are a key element for parenteral packaging and drug administration systems, therefore they have to fulfil strict criteria in terms of chemical and functional performance.

In the growing area of biosimilars and biologics primary packaging solutions must provide an optimised extractables and leachables profile. In most cases, these drugs are administered via prefilled syringes to ensure the highest level of safety for sensitive biosimilars and biologics. This is a crucial factor with regard to storage and packaging. The increasingly specialised demands for the primary packaging material performance drive the developments of high-quality components.

Components for prefilled syringes, such as barrels and plungers, in many cases have to be siliconised to ensure low break-loose and smooth glide forces. However, there are applications of closures and pharmaceutical components where siliconisation is not a preferred method of surface treatment. This is especially true for biologics and biosimilars, which consist predominantly of therapeutic proteins and, as such, may have undesirable interactions with a siliconised surface. Thus, more suitable alternative methods are applied.

For therapeutic proteins, the exact chemical make-up and three-dimensional conformation can influence the efficacy of the drug. The interaction of proteins with silicone oil can present a risk to the safety and efficacy of therapeutic proteins. Conformational changes, degradation and aggregation can lead to the inefficacy or immunogenicity of the protein, ultimately impeding or preventing the success of the drug. Therefore, many manufacturers of biologics or biosimilars are already relying on fluoropolymer coated closure solutions today. The reduction and elimination of silicone oil and silicone-oil-based subvisible particles (SbVPs) has become a legitimate concern for any pharmaceutical and medical manufacturers.

ABOUT THE COMPANY

Datwyler Group is an international supplier of state-of-the-art industrial components with leading positions in global and regional market segments, with a global manufacturing footprint on three continents, sales in over 100 countries and more than 7,000 employees. In its Sealing Solutions division, Datwyler provides customised sealing solutions to manufacturers and companies which operate in the healthcare and automotive industries, among others. The products and services of Datwyler are built on high-quality material, innovative technologies, outstanding engineering and process know-how.

ABOUT THE AUTHOR

Massimo Mainetti is Head of Strategic Marketing at Datwyler Sealing Solutions. He holds a Master's degree in business administration from the University of Milan, Italy. In January 2015, he joined the global sales team of Datwyler Pharma Packaging as Key Account Manager, Injection-Systems. Since June 2017, he has been acting in his current position. He brings to the company broad experience from diverse backgrounds in key account managing, distribution and strategic and international marketing.