OWEN MUMFORD
Pharmaceutical Services

UNISAFE® 2.25: SEAMLESSLY TRANSITIONING TO NEW-GENERATION BIOLOGICS

In this article, George I'ons, Head of Product Strategy and Insights at Owen Mumford, discusses the benefits of subcutaneously administering new drug formulations, and the factors that manufacturers need to consider when designing delivery devices.

As new-generation biologics increase in volume and viscosity, developers of drug delivery devices must revisit previous designs to accommodate new formulations. If these drugs could be subcutaneously administered, this would help to alleviate some of the pressure on healthcare systems, as this route is more suitable for home administration than intravenous drug delivery. However, to ensure effective administration outside of a healthcare setting, it is critical that manufacturers develop drug delivery solutions with the needs of patients and carers in mind, as well as healthcare professionals. Regardless of the benefits, patients may struggle to adhere to therapies if drug delivery is too painful or difficult, if the procedure is too complex or lengthy, or if they have to inject frequently. Human factors specialists and design engineers must, therefore, ensure optimal comfort, ease of use and safety in delivery device design, especially when adapting to the challenges of increased volumes and viscosity.

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Figure 1: UniSafe® 2.25 is the latest addition to the established UniSafe® platform.

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Resolving this challenge was the impetus for UniSafe® 2.25, the latest addition to Owen Mumford Pharmaceutical Services' established UniSafe® platform (see Figure 1). For subcutaneous administration, standard prefilled syringes (PFSs) and safety devices have been designed typically for 1 mL fill volumes and a viscosity that is under 10 cP. The UniSafe 2.25 safety device is designed to contain 2.25 mL PFSs, which are now being developed for higher volume and viscosity drugs, usually biotherapeutics.

CONTROLLING INJECTION TIME AND FORCE

Drug viscosity has a significant impact on the injection experience. To help ensure that patients have as little discomfort as possible, it is recommended that injection force does not exceed 10 N and that the procedure is no longer than 10–15 seconds, as human factors data show that patients typically struggle to continue holding a device in place after this duration. When viscosity is higher, it can be difficult to remain within these parameters. Prefilled safety syringe devices facilitate injections by allowing patients greater control over force and speed, and to an extent, the level of pain. To ensure easy operation, the UniSafe 2.25 device has a large comfortable plunger head and a smooth, integrated finger flange. In particular, these features assist patients who may have additional difficulty with injecting biologics, due to impaired strength or dexterity.

PREVENTING DRUG WASTAGE

As biologics often require small dosage volumes, it is critical that patients deliver the full dose and that the device prevents any possibility of drug leakage and wastage. This is a real concern for manufacturers as well, since biologics are often costly. One method of preventing leakage is to ensure that the syringe plunger at the rear of the device cannot be removed, and this serves the additional purpose of preventing tampering and possible multiple use. Drug wastage can also happen in the supply chain during transit as internal springs, which are typically used in safety syringes to activate the safety mechanism, can cause the device to activate accidentally before reaching patients. This is one of the reasons why the UniSafe 1 mL safety device was developed without a spring – a first for this type of product – and the 2.25 iteration retains this valuable feature. A further benefit of a springless device is that patients have clear visibility of the syringe contents before administration, and can check for drug clarity and that the dosage has been delivered fully following injection.

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PROTECTION FROM INJURY

It is important that medical devices used for self-administration are intuitive, which is why the injection technique for UniSafe 2.25 is the same as a conventional syringe. The injection procedure for both the 1 mL and 2.25 UniSafe designs are also the same. The product includes a safety shroud, which fully encases the needle and is automatically positioned as the user carries out the injection. When the plunger is fully depressed, the device's safety mechanism is automatically deployed and the needle retracts into the safety shroud. In compliance with sharps safety regulations, patients and users are immediately protected from the risk of needlestick injury as the needle is no longer exposed once injection is complete. As the mechanism is automatic or "passive", there are no additional instructions or techniques; patients can simply carry out injection as usual.

MANUFACTURING SIMPLICITY

As well as being simple to use, UniSafe 2.25 allows for a simplified manufacturing process. Adding a spring to a safety syringe device is complex as it must be done under high tension, so removing this element is highly advantageous for manufacturers. The product has only five moulded plastic components, which can be assembled easily with a PFS to create the final combination product. To allow pharmaceutical manufacturers a wider choice of suppliers, UniSafe 2.25 is compatible with ISO-standard small round flange and cropped flange PFSs. For viscous biologics, smaller gauge needles with a large diameter facilitate delivery, but patients may remove the device too early if they experience pain, and fail to fully deliver the dose. 29 G or 27 G needles, or even 25 G needles, are therefore most commonly used for subcutaneous injections, while thin-wall needles have been developed for highly viscous formulations to assist the flow of the drug in needles of a small diameter.

To encourage patient self-administration, there is an increasing focus on reformulating intravenous drugs for subcutaneous administration. However, the design of a drug delivery device must be given appropriate attention for subcutaneous administration to be effective and to encourage compliance. Although the molecular structure of biological drugs makes subcutaneous injection a preferred route of administration, the viscosity of these drugs can make comfortable injection challenging. As a result, the vast benefits of biologics may not be gained fully if delivery devices do not allow for a smooth injection procedure that is as intuitive as possible, for patients, carers and healthcare professionals alike. As more discoveries are made in this area of drug development, drug delivery device designers must rise to the challenge of providing innovative devices that enable a seamless transition to new formulations.

ABOUT THE COMPANY

Owen Mumford is a medical device manufacturer that develops products for its own brand and custom device solutions for pharmaceutical and diagnostic companies. Owen Mumford provides research, design and manufacturing capabilities for device production.

ABOUT THE AUTHOR

George I'ons is Head of Product Strategy and Insights, having worked at Owen Mumford since 2006. His current focus is on deciphering the rapidly changing pharma and biotech sectors in relation to their needs for combination products. In his previous roles in business development, he worked closely alongside the research and development team to develop devices for a variety of global pharma and diagnostic clients. Prior to Owen Mumford, Mr I'ons worked for Abbott in marketing roles in Germany, focusing on its diabetes business.

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Evolving
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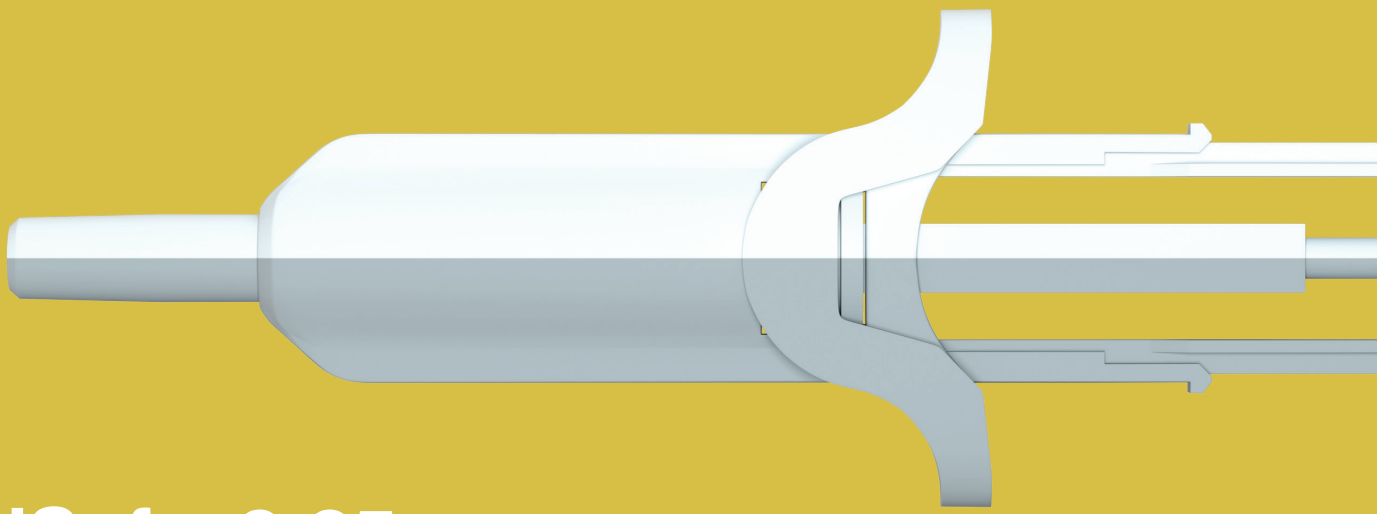

UniSafe® 2.25

Spring-free simplicity for higher volume formulations

A springless, passive safety device for 2.25mL pre-filled syringes, designed for simple assembly and use.

From concept to reality. Find out more at ompharmaservices.com/unisafe-2-25/

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