What if we had a simple and effective way of reconstituting and administering lyophilized products for infusion by a user in a home environment?

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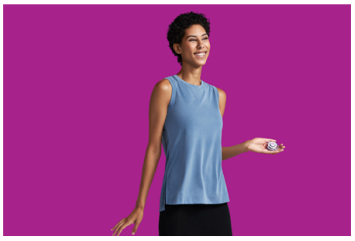
NEWSLETTER

The Enable Injections July / August blog topic is on the need for a simple and effective way of reconstituting and administering lyophilized products by a user in a home environment. The full blog article can be found here on the Enable website. An excerpt is below, along with recent announcements and upcoming events. There are many exciting developments at Enable as 2019 progresses.



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Kind regards,

The Enable Injections Team

The Enable Blog

The Need for Advanced Delivery Reconstitution Systems

Seven of the ten top-selling prescription medicines in 2018 are classified as biologic therapeutics[1]. Since the first biologic drug product was commercialized in 1986, the development of biologic therapeutics has grown due to the increasing availability of genetic information, disease processes, and manufacturing processes.

Biologic therapeutics can be made up of sugars, proteins, nucleic acids, or combinations of the three, as well as living cells and tissues. These types of therapeutics are large, complex molecules, which may be difficult to transport and store without jeopardizing the effectiveness of the therapeutic for the end-user. To improve stability, shelf-life, and speed-to-market, many biologics will be lyophilized (freeze-dried). Lyophilized medications require reconstitution at the time of use, adding additional preparation steps for the user.

Why Reconstitution?

Reconstitution is the process of mixing a dried therapeutic with a sterile diluent to reformulate it into liquid form before it is administered. Reconstitution methods require several steps and typically include systems ranging from a vial adaptor to vial-to-vial systems to advanced dual chamber reconstitution systems.

This process typically involves manual extraction of diluent using a syringe and transfer needle from one vial and transfer of this diluent to the vial containing the lyophilized product. Once transferred, the contents are mixed until the mixture is fully reconstituted. In some cases, this process can take up to a half hour and require a significant amount of attention by the user. The reconstitution process is typically performed by

a trained healthcare provider, but may be performed by patients and caregivers.

With the general movement of therapy from the clinic to the home, there is a need for a simple and effective way of reconstituting and administering lyophilized products by a user in a home environment.

Prevalence of Lyophilized Therapeutics

Currently, 16 percent of the top 100 pharmaceutical drugs are lyophilized[2] and 25 percent of the biologics market is expected to be lyophilized in the coming years[3].

More than 30 percent of the FDA-approved parenteral therapies are lyophilized[3]. The market is growing for biologics and the storage demands are increasing. Roots Analysis values the market for novel drug reconstitution systems to be $1.5 billion USD by 2025[4], not counting the cost of the drug in the valuation, driven by more complex drug formulations emerging on the market.

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