Subcuject

WEARABLE INJECTORS: THE PERCEPTION OF INHERENT EXPENSE AND COMPLEXITY

There is a widespread belief that wearable injectors are too expensive and complex to really take off as a commercially viable method of drug delivery. Here, Jesper Roested, Chief Executive Officer of Subcuject, tackles the causes of this belief, and explains why it is not truly the case.

Any discussion on wearable injectors is almost inevitably going to start with the rise of biopharmaceuticals. It is these novel therapies, both with huge potential therapeutic benefits and significant practical challenges that will, when formulated for subcutaneous delivery, drive the growth of the wearable injector market. A number of biologic therapies will, by their nature, have high volumes and viscosities, making it increasingly apparent that a standard pen or autoinjector device is not a suitable administration system for these drugs. At the same time, the pharmaceutical industry's shift towards a patient-centric – and more cost-effective – model means that many of the biologics in development are targeting subcutaneous at-home self-administration rather than intravenous (IV) administration in a clinical or hospital setting. Thus, wearable injectors are the natural home for these novel medicines.

At-home delivery is a priority for the modern-day pharma industry, not only because it is easier and more convenient for patients, but because professional healthcare systems are straining under the weight of a growing and ageing population. Reducing the burden on healthcare systems, both in terms of patients needing clinical-setting treatment and financial expense, is therefore a focus. Wearable injectors facilitate this aim by moving treatment into the home and being a relatively inexpensive way to administer large volumes.

At present, there are many wearable injector delivery systems in development, but very few actually approved and marketed. It is a significant challenge to design and develop a system that meets the necessary criteria:

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- Worn on the body
- High delivery force
- Low and controlled delivery speed.

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systems and electronics. In some cases, because the electronics are already in place, device developers have elected to add programmability and connectivity into their devices. For some drugs and indications this will prove valuable, however in many others the patient may be better served by keeping the device as simple, and as inexpensive, as possible, simply delivering higher volumes of drug over a longer period of time than is possible with a pen injector or autoinjector.

ARE WEARABLE INJECTORS COMPLEX AND EXPENSIVE?

There is a notion in the industry that wearable injectors are inherently complex devices. This is certainly the case for some devices currently in development, possible reasons being that:

- The patients may have to load the drug into the device themselves.
- The patients may have to assemble the device themselves.
- The patients may have to set the injection program or settings themselves.

Furthermore, the more complexity is added into a device, the more the device becomes difficult to use, expensive and/or bulky. As such, complexity and extra features constantly need to be weighed up as a trade-off against these other factors. Often as not, solving one of these problems exacerbates another.

A key factor in the cost and logistical difficulties of several proposed wearable injectors is the electronics. Electronics and batteries are a poor match for the cold storage required by many biologics and also pose environmental concerns around disposal.

In practice, many of the wearable injectors currently in development will have a contract manufacturing organisation (CMO) price of US$20–30 (£16–24) at volume production. At this level, the unit cost to pharma companies is simply too high for many drugs, even when considering those needing only bi-weekly or monthly administration. This complexity, either for the patient or in manufacturing, and anticipated high cost is leading some to the belief that wearable injectors may not be viable for many drugs, causing pharma companies to prefer working with established pen injector and autoinjector systems, despite them being naturally less-suitable.

CAN A WEARABLE INJECTOR BE AS SIMPLE AND INEXPENSIVE AS AN AUTOINJECTOR?

Even in the face of opposition, there is no doubt that some biologic therapies will require complex and expensive advanced delivery systems. However, this is not a universal truth. For many applications, a simple-to-manufacture, simple-to-use wearable injector that is, in essence, nothing more than a prefilled syringe and drive system adhered to the skin that is capable of high-volume, low-speed injection will perfectly serve the needs of both drug and patient. Such a device, provided at a low cost threshold, will therefore be a highly competitive offering in this up-and-coming market.

> "Subcuject's solution is purely based on the powerful, and very inexpensive, natural process of forward osmosis, not using any electromechanical or electronic parts at all."

A "simple-to-use" device is key. The success of the autoinjector is in large part due to the fact that, for the patient, its use is an incredibly easy concept to grasp. A wearable injector should therefore aim to be just as simple. This means that, ideally, a patient should have to do nothing more than unpack the wearable injector, stick it on their body and press a single button. All other functions, such as needle insertion, injection and needle retraction, should be handled by the device itself.

In many cases, in order for it to be seen as advantageous for the pharma or biotech company to adopt a wearable injector solution in the first place, the device should have a unit cost to pharma roughly equal to that of a standard autoinjector. Similarly, the wearable injector should use familiar materials for its primary packaging, ideally standard components if at all possible so that it can use standard filling lines. Furthermore, it needs to take into account the need for cold-storage and its ultimate disposal after use.

Subcuject is developing such a device and is currently in the process of maturing the concept (Figure 1). Subcuject's solution is purely based on the powerful, and very inexpensive, natural process of forward osmosis, not using any electromechanical or electronic parts at all. Whilst the core of the

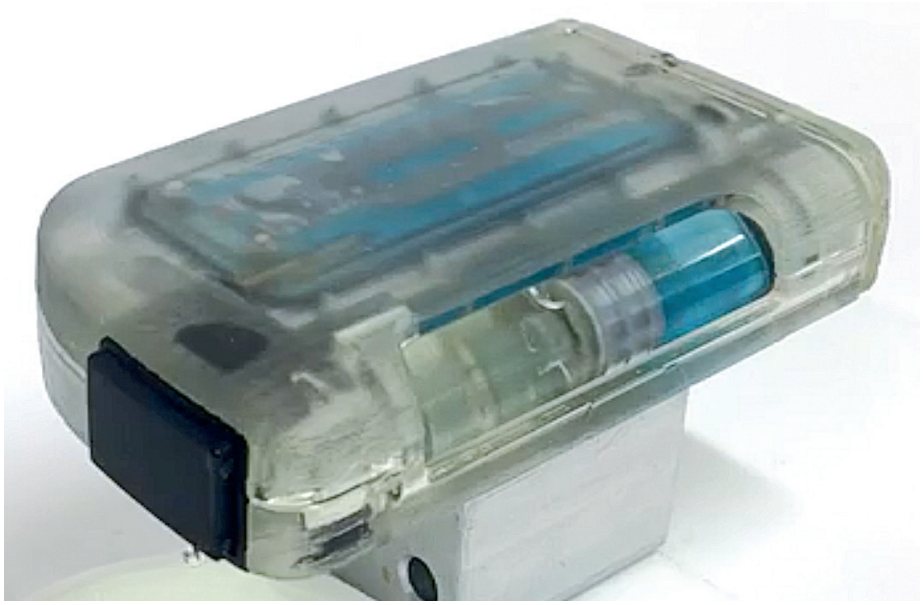

Figure 1: Functional model of the Subcuject device.

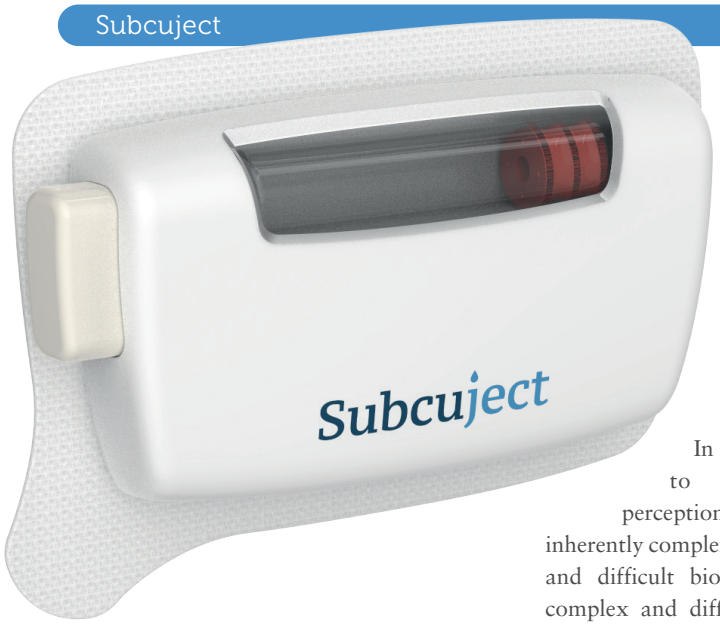

Figure 2: Rendered image of a potential final device.

system is completely without electronics, electronics for e.g. connectivity could be added in a later generation.

The near future therefore holds the promise of prefilled, disposable, low-cost, small, simple-to-manufacture, simple-to-use wearable injectors for the delivery of biologics (Figure 2). Such devices will be suitable for at-home administration, make sound financial sense to both payers and pharma, and will be an attractive option for patients and healthcare providers.

CONCLUSION

In conclusion, it is necessary to modify the existing perception of wearable injectors as inherently complex and expensive. Complex and difficult biologics may well require complex and difficult devices, but this is not a universal truth. It is entirely possible for a wearable injector to be simple, both in terms of use and manufacture, and inexpensive, with unit costs to pharma reaching down towards $5, similar to an autoinjector, rather than the present $20–30. Subcuject is working towards such a device and is looking forward to revealing further details as the concept matures.

ABOUT THE COMPANY

Subcuject develops an innovative and proprietary wearable device platform for bolus injection. It is a virtual organisation, working closely with external experts and specialist organisations. The management team and board of directors has decades of collective experience and a long track-record working in medical devices, pharma and drug delivey. Subcuject is a privately held company located north of Copenhagen, Denmark.

ABOUT THE AUTHOR

Jesper Roested, Chief Executive Officer of Subcuject, holds an MSc in Medical Electronics and Physics and has 25 years of business experience. Mr Roested has primarily held business development and management roles in the life science industries, including seven years as a partner in a venture capital fund, specialised in medtech.