

## Drug delivery devices - does the toolkit need changing?

Getting drugs into the body to the target organs and tissues is not always easy. The concept of the swallowable pill that can survive the hostile conditions of the human digestive tract and yield its payload throughout the body at safe and efficacious levels is an ideal that cannot always be realized.



Instead, over the last century, a range of devices has evolved which are designed to deliver pharmaceutical ingredients more precisely, overcoming natural barriers and avoiding the body's defences. So, in the standard drug developer's toolkit, we have the hypodermic needle syringe and its close relatives the injector pen and autoinjector for percutaneous delivery into dermis, muscle and bloodstream. Alongside these are the inhalers: some relatively simple, like the pressurised metered dose inhalers; and some more complicated, such as breath-actuated dry powder inhalers, all of which are designed to send drugs to the lungs without premature deposition en route. And for those more specialised applications, the toolkit contains such familiar items as the eye dropper, the skin spray can and the medicated dressing.

For many in the Pharma industry, these devices add an unwelcome cost and complexity to what is already an exceedingly challenging drug development process. For the patient, complicated instructions, unpleasant side effects and difficulty in using devices discreetly may mean they are regularly incorrectly used; and of course without proper use, all the proven clinical benefits of the drug are to no avail.

So is the toolkit good enough or does it need to change? Whatever your views are on the subject, there are signs that the industry is waking up to the possibility of some radical new approaches to drug delivery, driven by a number of specific needs. Here are four examples of recent additions to the delivery toolkit:

### ▸ Wearables

Wearable drug pumps have been around for a while, but they are getting more sophisticated, less obtrusive and are now delivering drugs other than insulin. Take for example Chrono Therapeutics' cigarette smoking cessation aid. This low profile wearable device automatically delivers precise doses of nicotine at specific times of the day to coincide with the user's urge to smoke.

### ▸ Intelligent devices

Sensing, communicating and controlling are three ways in which drug delivery devices are becoming more 'intelligent' – and that usually means the incorporation of electronics into what were previously passive mechanical devices. Sagentia's VeriHaler

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technology is a good example, utilising an acoustic sensor and advanced algorithms to analyse a patient's inhalation profile. Bluetooth connectivity to a smartphone allows real-time feedback to the patient while usage data can be relayed to physicians to monitor adherence.

#### ▸ New routes

With the increasing costs, timescales and regulatory hurdles to new drug development, many manufacturers are asking the question of what more can be done to extract value from their existing portfolio of molecules. 'New uses for old drugs' is one option, but another is 'new routes for existing drugs and existing uses'. Could clinical safety and efficacy be improved by taking what used to be a systemically delivered drug and delivering it locally, or by changing the gateway to systemic delivery? Recent examples are Sanofi and MannKind's powdered insulin for delivery to the lung and 3M's hollow microneedle technology for intradermal delivery. Both of these offer new routes for delivery of existing drugs – the former offering an alternative to the traditional insulin injection and the second offers a way of breaching the skin barrier in a minimally-invasive way.

#### ▸ New propulsion mechanisms

Whatever the clinical and commercial benefits of the shift from small molecule drugs to high molecular weight biologics, an unintended consequence has been the increase in viscosity, rendering percutaneous injection more difficult to achieve quickly and comfortably. Addressing this issue through new routes of administration is one option already discussed, but another strategy is to take a look at the propulsion engine and fluid train. One example is Steadymed's battery expansion which allows high volume or viscous liquids to be discreetly administered over hours or days. Other examples include Bepak's liquified gas and Portal Instrument's motor-driven technologies.

It is true that for many drugs, the standard spring-loaded autoinjector or the basic pressurised inhaler will suffice, at least in the short to medium term. However, in the long term, it is likely that these devices will be replaced or at least augmented by new technology. This technology will optimise dosing, simplify and motivate proper use, and communicate valuable data to patients, caregivers and payers. Given the inevitability of technology change, the question for Pharma companies is not if to act, but how and when to act. For example, whether to be a prime mover or a fast follower? Keep a watching brief or selectively invest? Innovate internally or out-source? Doing nothing is a risky strategy as any victims of disruptive change can attest.