

EDITORIAL COMMENT



I'm pleased to present to you here the first ever issue of ONdrugDelivery Magazine to focus wholly on the topic: "Wearable Bolus Injection Devices". These devices, also known as patch pumps or high-volume injectors, typically carry out automated subcutaneous (SC) delivery of large volumes of potentially highly viscous drug formulation whilst worn like a patch, adhered to the skin. They are distinguished from long-term infusion devices which have existed for many years now in that, rather than delivering a constant amount of drug per minute or sequential small regular doses in order to maintain specified drug plasma levels over time, wearable bolus injectors deliver a single bolus SC dose and are then removed and disposed of or recycled.

I've heard of, read about and written on a number of "hot topics" over the decade or so since drug delivery became my career focus – some of them weren't hot at all it turned out, others were important but destined for failure, and a fair few of them have changed the pharmaceutical industry forever. I have never been able to say this about a class of novel (pre-approval) drug delivery systems with such certainty before, but wearable bolus injection devices belong in the latter category. They will change the pharmaceutical industry forever, and they will do it relatively soon.

Why so sure? In short, this class of devices has found the sweetest of sweet spots for a major technological innovation. On one hand, a cluster of wearable bolus injectors are coming through their own development process timed perfectly to be available and ready to fulfil a huge need in the market as it arises – in this case the need comes from the wave of biologics moving through the latter stages of their clinical development towards approval, combined with the rapidly increasing emphasis being placed on Human Factors and Usability, and the mere acceptance of self/home subcutaneous administration evolving into a requirement. On the other hand, wearable bolus injectors can fulfil this massive market demand without themselves needing to be especially far advanced, technologically-speaking, from their predecessors. No wild leaps into the unknown. Clever design approaches in safe pairs of hands have enabled companies to bring forward this new class of devices very rapidly. To a greater or lesser extent many of them are able to avoid

the usual detailed and lengthy regulatory requirements by using, or only incrementally modifying, existing components, especially those that contact the drug formulation itself. So a game-changing new class of delivery systems can be realised using highly intelligent and innovative, yet relatively incremental technological advances.

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More detailed explanations as to exactly why this is such a particularly important area of drug delivery today and why it will have such an impact can be found in the articles that follow in this issue, beginning with the Pharma Perspective article from Paul Jansen, Vice-President, Medical Device Development at Sanofi Aventis (Page 7). Jansen is positive in his assessment of the potential of what he calls "large volume delivery (LVD) devices" saying that industry is competing aggressively for access to LVD technology.

I'm very pleased indeed to have such a great spread of device feature articles in this issue, contributed by the majority of the main players in this closely competitive sector of the injectable drug delivery sector. Before going on briefly to introduce those companies and technologies which do appear here in this issue, I should mention a couple of those which have been unable to contribute. Firstly, BD is developing its MicroInfuser – recently rebranded as the Libertas Patch Injector – a single-use, disposable system, hands-free during drug delivery, the duration of which can range from seconds to several minutes. Secondly, Ratio Drug Delivery, which said it couldn't contribute to this issue for confidentiality reasons, is developing NuPrivo-SC, which it calls a "bandage with a

button". NuPrivo-SC is due to enter clinical trials shortly, making it the most advanced in Ratio's portfolio of patch-injection devices, which includes an intradermal injector and a continuous infusion system.

The first of the companies contributing to this issue which should be mentioned is Unilife, to which I'm most grateful for its strong support for this edition of ONdrugDelivery as our Outstanding Issue Sponsor. Company CEO Alan Shortall has written an insightful piece (Page 8), which sets Unilife's two electronic wearable bolus injectors – Flex-Therapy and Precision-Therapy – in the context of an integrated offering as part of Unilife's highly customisable range of injectable drug delivery devices and safety syringes.

Continuing the theme of wearable-bolus injection devices as part of an integrated drug delivery offering, Graham Reynolds of West Pharmaceutical Services argues that as self-injection at home becomes more commonplace, it becomes increasingly clear that there is no "one size fits all" device solution (Page 26). Preferences differ from one patient to another, with some people feeling more confident and in control using a "naked" prefilled syringe with simple needle-safety device, for example, while others prefer everything to be taken care of by a wearable injector. But Reynolds also points out that an individual patient's preference could change over the long time (perhaps a lifetime) that they could be taking an injected therapy for a chronic condition. For each pharmaceutical product, a variety of integrated injection devices is essential, therefore, to cater for these changing inter- and intra-patient preferences.

Enable Injections is taking a unique approach as it races towards US approval with its wearable bolus injector. I had the privilege of meeting Enable Injections' Founder and CEO, Mike Hooven, earlier this year after one of Management Forum's many excellent London conferences. I was genuinely inspired, not only by Mr Hooven's formidable track-record in other medical device-related business endeavours, but also by the complete grasp he has of very precisely where and why wearable injection devices slot in to the current parenteral drug delivery arena, and also by the passion he has for his current project,

the mechanical Enable Injection Device. Enable's very high volume, small, wearable bolus injection device is described in this issue on Page 30, together with the reasons why Enable has avoided a prefilled system and gone for a patient-loaded drug transfer system. These reasons are backed by robust data from numerous intensive user studies.

All of the drug delivery technologies featured in this issue of ONdrugDelivery have their own unique and particularly interesting characteristics and, for SteadyMed's PatchPump device (Page 22), this is the E-Cell, which provides the driving force for delivering the drug. The E-Cell is similar to a normal alkaline battery and it does generate the electric power for the PatchPump's electronics. However, unlike a normal alkaline battery, as current flows the E-Cell's electrolytic materials expand in a flexible housing, thus generating a mechanical force which drives the delivery of drug formulation from the device to the patient. Unlike the other companies featured in this issue, SteadyMed is developing its device for incorporation into its own specialty pharma business model. The lead internal product development programme is treprostinil

PatchPump for pulmonary arterial hypertension, for which US NDA submission is planned for the second half of 2015.

The final wearable bolus injector technology to introduce here is the result of a successful classic pharma/drug delivery partnership. Swiss device company Sensile Medical together with US pharmaceutical company scPharmaceuticals are collaborating on the development of a bolus injector device built around Sensile's SenseCore micropump, for the delivery of scPharmaceuticals' pipeline of products (Page 16). The companies highlight advanced safety features made possible only with their pump mechanism and electronic device. The focus is on enabling a portfolio of pharmaceutical products suitable for "anytime-anywhere" delivery – specifically SC administration via a wearable device – which, among other applications, could either completely replace, or supplement, IV delivery.

Also featured in this issue of ONdrugDelivery Magazine is a brief article from Gerresheimer on the manufacture of glass primary parenteral drug containers (Page 34). As mentioned at the top of this piece, many wearable bolus injectors use

existing components, including a standard primary drug container, to which the same rigorous inspection standards will apply during scale-up to commercial manufacturing.

At the rate things are moving, full-scale commercial manufacturing of approved and marketed wearable bolus injectors is just around the corner.

The next issue of ONdrugDelivery Magazine focusing wholly on this exciting topic will be out in July 2015. By that time, as well as having published various further issues, each focusing on specific topics within drug delivery, such as "Prefilled Syringes", "Transdermal, Microneedles & NFIs", "Ophthalmic Delivery" and others (see the Editorial Calendar on Page 15), ONdrugDelivery Magazine will have also celebrated its Tenth Anniversary (in early 2015). To coincide with our one decade milestone, we are launching some exciting new information and intelligence offerings for you, fit for the next decade to come, all still tightly focused as ever on the global drug delivery industry ... watch this space!!

Guy Furness

Publisher, ONdrugDelivery Magazine

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