IMPRINT in print
Reinventing injections through innovation
The Newsletter of Imprint Pharmaceuticals Ltd Vol 1 Issue 1

# Particulate injections made easy using Imprint technology

**Given that conventional needles and syringes have been designed for Newtonian, non-particulate fluids, it is not at all surprising that when used for the delivery of particulate formulations, these devices are frequently hampered by a variety of injectability problems. Not least among them is device clogging, which can be a serious issue as it leads to inaccuracy of injection, with potential clinical consequences.**

The pharmaceutical industry is now well aware of the enormous potential microparticulates hold as the basis for long-acting injections, and the number of such products in development escalates year on year. Thus, the need for an effective solution to the delivery issues with which they have become associated has become increasingly apparent.

Imprint has released exciting data showing that its new injection devices meet that need, reducing clogging during injection of microparticulate formulations. The devices have the potential to transform microparticulate formulations by substantially increasing the dose that can be injected without the risk of a blockage occurring.

"Our clients are genuinely excited by these developments," says Kevin Maynard, director of business development. "Our devices will substantially improve the delivery of their particulate formulations. "By improving delivery, there is a direct and significant improvement in clinical performance. Higher doses can be delivered, longer-acting microparticulate therapies can be developed, and even the problematic initial burst phenomena can be reduced. The devices can only enhance the therapeutic benefit to the patients," he explains.

The newly released data show that some device combinations can increase the deliverable concentration of microparticulate formulations to over three times that which can be reproducibly delivered using standard needle injection devices. This is a substantial increase, with certain particulates being able to be injected at a concentration up to 750 mg/ml through a 27-gauge needle.

"Importantly, these devices usually can be used without any changes to an existing formulation, reducing the regulatory implications. The devices are in various states of development with some having been submitted for 510k approval in the US, whilst others are still in the development process," Dr Maynard notes.

## Analysing the mechanism of clogging

Particulate formulations have highly variable characteristics. There are floating and sinking particulates, large and small particulates, and hydrophilic and hydrophobic

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BREAKING NEWS

## Partners test DepotOne in clinic

Pharmaceutical companies that have completed initial evaluation of the DepotOne device have consistently been impressed by its performance. Imprint is delighted to announce that a number of major global pharmaceutical firms have now purchased substantial quantities of DepotOne needles, and are using them for the delivery of products undergoing large-scale clinical trials.

"Although we are unable to disclose the details of these clinical trials, we can confirm that each partner has taken ownership of significant volumes of DepotOne needles, and the trials are underway," says Imprint's Dr Kevin Maynard. "On successful completion of the trials, the companies may decide to select DepotOne for further development with their products right through to the market."

"The markets for each of the products currently in the clinic with DepotOne are both substantial. If DepotOne is taken to market with either one of them, there would be a requirement for many millions of needles annually," Dr Maynard notes.

## IN THIS ISSUE

# DepotOne launched in Europe

Imprint Pharmaceuticals is very pleased to announce that DepotOne, its advanced needle technology for the injection of complex formulations, is now available for sale in Europe. The news follows the recent granting of CE Mark approval for DepotOne as a medical device by the European regulatory authorities.

"This is an important milestone for Imprint, which strengthens our position as a leading provider of technologies that enhance and enable complex injectable formulations," said Dr Kevin Maynard, who co-founded the company in 1998. "Following seven years of development work, the device is now proven and available on the European market. We can now look ahead to approvals in other regions worldwide"

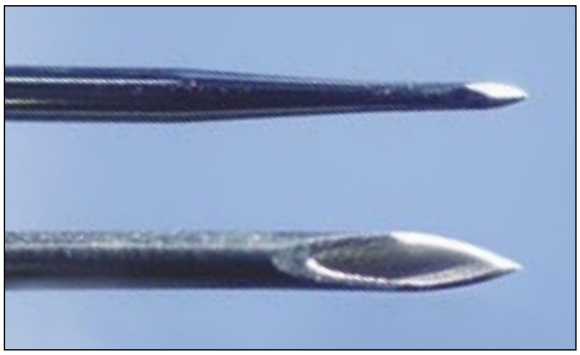

**Figure 1: The DepotOne's tip (at the top), compared with a conventional needle.**

The DepotOne needle is designed to deliver highly viscous materials while avoiding the need to resort to an unacceptably large needle. Formulation scientists have been delighted by the extra fluidic capacity provided by the DepotOne needle, which enables them to deliver larger doses and move beyond the current limits of injectable formulations.

For longer-acting therapies and products that must achieve higher blood concentrations, DepotOne can become the cornerstone of successful development. Marketers of these types of complex formulation are fully aware of the significant perceptual damage that large needles can cause to the reputation of an injectable therapeutic product. Without modifying the formulation itself, DepotOne offers them a commercially attractive and technically elegant opportunity to reduce the impact of the large needle issue so the positive aspects of their product can be highlighted.

## CONFERENCE ATTENDANCE

Imprint Pharmaceuticals will be attending and/or speaking at the following forthcoming conferences. If you would like to arrange a meeting at any of these events, please contact us.

*February 14-15 (London, UK)*

- **SMi's 4th Annual Controlled Release Conference**

*June 18-22 (Miami, Florida, USA)*

- **32nd Annual Meeting & Exposition of the Controlled Release Society**

*September 26-28 (Manchester, UK)*

- **British Pharmaceutical Conference 2005**

*November 6-10 (Nashville, Tennessee, USA)*

- **2005 AAPS Annual Meeting and Exposition**

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particulates. This complexity means that needles and syringes can become blocked via a multitude of different mechanisms. Recognising the complex nature of these systems, and the enormous advantages to be gained from understanding them, Imprint has devoted significant resources to building its expertise on the subject.

Indeed, through meticulous research, the company has already discovered that there are more than 15 such needle-clogging mechanisms, each requiring a different needle design feature to reduce the risk of blockages. A multiplicity of needle designs are possible, combining different features.

Identifying the right needle to use is by no means a straightforward exercise so, putting its knowledge into practice, Imprint has developed a unique testing system. Given a particulate formulation, Imprint's analysis can identify the mechanism by which that formulation is most likely to clog a needle and syringe.

Since the mechanism of blockage depends on the formulation, the optimum delivery of microparticulates is achieved by combining the formulation with the right device. So the tests are the critical first step in identifying the right needle to use. Clients are also already using them to facilitate the development of unique devices.

## CONTACT US

To find out more about any of the news and developments reported in this issue, please contact Dr Kevin Maynard, Director of Business Development.

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# Bespoke needle adds value

Imprint Pharmaceuticals is pleased to report that a growing number of clients are asking it to customise their needles and syringes, as well as other fluidic devices, for the optimal delivery of difficult-to-deliver solutions.

The needle customisation service enables clients to add significant value to their products, maximise their potential by improving delivery profiles. For example, the process can result in reduced volume and blockage whilst minimising pain and trauma. These clinical benefits translate directly to protectable commercial advantage.

Imprint has carried out successful projects with many of the most awkward injections available, making it uniquely qualified to deliver commercially advantageous solutions rapidly.