

Development of delivery device technology to deal with the challenges of highly viscous mAb formulations at high concentration

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Using delivery devices to deliver large volume mAb formulations by the subcutaneous route

Large volumes of high concentration mAbs can potentially be delivered subcutaneously (SC) by using delivery device injection technology. Currently most commercially available autoinjectors, although simple to use, are limited to ~1 mL injection with solution viscosities <20 mPas. Autoinjectors are under development that can handle greater volumes and higher viscosities, but from a practical size limitation probably will not be much larger than 3 mL injectors. The rapid injection, usually less than 10s for this larger volume, may require the use of rhuPH-20. A short review of the issues in development of such injectors and discussion of a particular technology are available (White & Harvey, 2014). Another technology that is very promising is the development of SC infusion patch devices, which can deliver large volumes (at least 5 mL) and high viscosity solutions over a period of time, usually 15–30 min. These devices are worn directly attached at the infusion site (not unlike a transdermal patch) and may have a separate wireless control device such as used in the OmniPod® pump patch system. This is relatively new technology and several companies are developing such technology. There is little in the peer-reviewed literature that discusses or reviews this technology for applications of mAb delivery. Some of the published literature discusses long-term SC infusion of insulin (Pickup, Keen, Parsons, & Alberti, 1978), development of pump patch systems that can deliver 2 mL of insulin (Schaepelynck et al., 2011), and some of the technical challenges that must be met to develop such systems (Skladany, Miller, Guthermann, & Ludwig, 2008). There are trade commercial publications with several articles, many focused on a particular company's technology (see the recent issue 51 on bolus wearable injectors by ONdrugDelivery, July 23, 2014 as well as the introduction by Jansen, 2014).

Delivery of viscous solutions using a prefilled syringe

In some cases, it is desirable to deliver ~1 mL of a viscous mAb formulation using either a prefilled syringe or an autoinjector. Most autoinjectors commercially available can handle between 10 and 20 mPas viscous solution, but a more viscous solution may